قرار وزاري رقم (387/ 2025) لسنة 2025

بشأن تنظيم تسجيل وتداول الأجهزة والمستلزمات الطبية

وزير الصحة:

– بعد الاطلاع على أحكام المرسومين بقانون ونظام الخدمة المدنية وتعديلاتهما.

– وعلى أحكام القانون رقم 28 لسنة 1996 في شأن تنظيم مهنه الصيدلة وتداول الأدوية والمعدل بالقانون رقم 30 لسنة 2016 ولائحتيهما التنفيذية.

– وعلي القرار الوزاري رقم 13 لسنة 2022 بشأن إعادة تنظيم تسجيل وتداول الأجهزة والمستلزمات الطبية.

– وعلى القرار الوزاري رقم 9 لسنة 2025 بشأن ضوابط ولوائح تنظيم عملية الإعلانات الطبية للمراكز الصيدلانية وأماكن ومحال البيع في القطاع الأهلي.

– وعلى القرار الوزاري رقم 340 لسنة 2025 بشأن تنظيم إجراءات الافراج والتداول للمنتجات المستوردة الخاضعة لرقابة إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

– ورغبة في إعادة تنظيم تسجيل وتداول الأجهزة والمستلزمات الطبية بما يضمن سلامة تداولها.

– وبناء على مقتضيات العمل وما عرضه علينا السيد/ وكيل الوزارة.

قـــرر

مادة أولى:

يُقصد بالمصطلحات التالية المعنى المبين قرين كل من:

الوكيل المحلي: هي الشركة المحلية الممثلة للشركة صاحبة حق التسويق للأجهزة والمستلزمات الطبية والمرخص لها بيعها في دولة الكويت، ومسئولة عن جميع الإجراءات القانونية المتعلقة بها من بيع أو سحب أو إتلاف أو متابعة الأعراض الجانبية وخلافه داخل دولة الكويت.

المكتب العلمي: هو المركز الصيدلي الذي يقوم بتمثيل الشركة صاحبة حق التسويق في دولة الكويت ومسؤول عن المعلومات والإجراءات العلمية والفنية والتسويقية الأجهزة والمستلزمات الطبية.

الممثل المعتمد: هو الوكيل المحلي أو المكتب العلمي المعتمد أو فرع الشركة صاحبة حق التسويق المرخص من وزارة الصحة.

الشركة المصنعة: هي المنشأة التي يتم فيها تصنيع الجهاز أو المستلزم الطبي وفقاً لأسس التصنيع الجيد، أو مطابقة المعايير الدولية للجودة (ISO).

الشركة صاحبة حق التسويق: هي الشركة التي تحمل ترخيص الجهاز أو المستلزم الطبي وتتولى تسويقه سواء كانت المصنع القانوني المعتمد أو المتعهدة بالتسويق، وتكون مسؤولة مسئولية كاملة عن جودة المنتج ومأمونيته وفعاليته ومتابعته بعد التسويق وجميع الإجراءات القانونية المتعلقة به من بيع، أو سحب، أو إتلاف، أو متابعة الأعراض الجانبية وخلافه في جميع الدول التي يسوق فيها المنتج.

البطاقة التعريفية: يقصد بها أي بيان، أو معلومة مكتوبة، أو مطبوعة، أو مرسومة، أو مصورة وتشمل ما يلي:

1. البطاقة المثبتة / الملصقة على الجهاز، أو المستلزم الطبي، أو أحد حاوياته، أو أغلفته.
2. المعلومات الخاصة بالتعريف بالجهاز أو المستلزم الطبي أو الوصف الفني له.
3. المعلومات الخاصة بكيفية استخدام الجهاز.

بلد المنشأ: هي بلد الشركة المصنعة أو صاحبة حق التسويق الذي تصدر سلطاته الرقابية شهادة التداول الحر الجهاز أو المستلزم الطبي.

شهادة التداول الحر للجهاز أو المستلزم الطبي: شهادة صادرة من السلطة الرقابية المختصة بالدولة صاحبة حق التسويق أو الدولة التي يتم فيها التصنيع كاملاً أو جزء من تصنيع المنتج.

السلطات الرقابية المرجعية: تشمل السلطات الرقابية العالمية الصارمة مثل إدارة الغذاء والدواء الأمريكية US FDA))، الاتحاد الأوروبي (EU)، وزارة الصحة الكندية (Health Canada)، ووكالة تنظيم الأدوية ومنتجات الرعاية الصحية البريطانية (MHRA)، وكالة الأدوية والأجهزة الطبية اليابانية (PMDA)، الهيئة السويسرية للدواء (Swissmedic)، إدارة المنتجات العلاجية الأسترالية (TGA)، والوكالة الوطنية للمراقبة الصحية في البرازيل(ANVISA)).

الجهاز الطبي: كل آلة أو أداة أو جهاز تطبيق أو جهاز زراعة أو كواشف مخبرية أو مواد معايرة مخبرية أو برامج أو مواد تشغيل للأجهزة الطبية، أو أي أداة شبيهة أو ذات علاقة صنعت لوحدها أو مع أجهزة أخرى؛ تستخدم في تشخيص الأمراض أو الإصابات أو الوقاية منها أو مراقبتها أو التحكم فيها أو علاجها أو تخفيفها أو تسكينها أو التعويض عن الإصابات، وتستخدم كذلك في الفحص أو الإحلال أو التعديل أو الدعم التشريحي أو التأثير على وظائف أعضاء الجسم، ودعم أو تمكين الحياة (الوظائف الحيوية للإنسان) من الإستمرار، وتنظيم الحمل أو المساعدة عليه، وتعقيم الأجهزة والمستلزمات الطبية، وإعطاء المعلومات – لغرض طبي أو تشخيصي– المستخلصة من الفحوصات المخبرية للعينات المأخوذة من جسم الإنسان، وكذلك التي لا يمكن أن تحقق الغرض الذي صنعت من أجله في جسم الإنسان أو عليه بوساطة العقار الدوائي أو العامل المناعي أو التحولات الأيضية، وإنما تساعد في تحقيق مفاعيلها فقط.

الأجهزة المخبرية والتشخيصية: هي الأجهزة التي صنعت لتستخدم وحدها أو مع أجهزة أخرى في عملية تشخيص أو مطابقة أو متابعة الحالات المرضية من خلال إختبارات تجرى خارج الجسم الحي باستعمال عينات منه، وهذا يشمل الكواشف المخبرية وأوعية العينات والبرامج التشغيلية وأي مواد ذات علاقة.

المستلزم الطبي: المواد والمنتجات الطبية، المستخدمة في التشخيص، أو

العلاج، أو الاستعاضة، أو التقويم، أو حالات الإعاقة، أو غيرها من الإستخدامات الطبية للإنسان.

ملحق الجهاز أو المستلزم الطبي: أي مادة أو منتج يصنع خاصة لإستخدامه مع جهاز أو مستلزم طبي لتمكينه من تحقيق الغرض الذي صنع من أجله.

الإجهزة الطبية ذات الأشكال الصيدلانية: هي منتجات تحتوي على مواد أو مزيج من المواد (مثل بخاخات المحلول الملحي والقطرات المرطبة للعين وغيرها والتي تحقق تأثيرها الطبي الأساسي من خلال وسائل فيزيائية أو فيزيوكيميائية وليس عبر تأثيرات فارماكولوجية أو أيضية أو مناعية، وقد تحتوي أيضاً على مواد دوائية مساعدة.

المبادئ الأساسية Essential Principals: هي الإشتراطات التي يتم تطبيقها على جميع الأجهزة الطبية والكواشف التشخيصية، وتهدف إلى تحديد ووصف المبادئ الأساسية للسلامة والأداء التي يجب مراعاتها أثناء عمليتي التصميم والتصنيع وبناء على طبيعة الجهاز الطبي، ويتم تطبيق المبادئ الأساسية للسلامة والأداء وفقاً لإرشادات المنتدى الدولي لمنظمي الأجهزة الطبية المذكورة في الملحق المرفق بهذا القرار.

مادة ثانية: تصنف الأجهزة والمستلزمات الطبية إلى أربع فئات حسب خطورتها ومدى تأثيرها على مستخدميها على النحو التالي:

الفئة (أ): تشمل الأجهزة والمستلزمات الطبية منخفضة المخاطر مثل القطن الطبي والكراسي الطبية المتحركة كما هو مذكور في الملحق المرفق بهذا القرار.

الفئة (ب): تشمل الأجهزة والمستلزمات الطبية منخفضة إلى متوسطة المخاطر مثل حشوات الأسنان وأنابيب القصبة الهوائية المذكورة كما هو مذكور في الملحق المرفق بهذا القرار.

الفئة (ج): تشمل الأجهزة والمستلزمات الطبية متوسطة إلى عالية المخاطر مثل الواقيات الذكرية وشرائح تثبيت العظام وأجهزة التنفس الصناعي كما هو مذكور في الملحق المرفق بهذا القرار.

الفئة (د): تشمل الأجهزة والمستلزمات الطبية عالية المخاطر مثل أجهزة تنظيم ضربات القلب وصمام القلب ومحفزات الدماغ المزروعة كما هو مذكور في الملحق المرفق بهذا القرار.

مادة ثالثة:

تصنف الأجهزة التشخيصية إلى أربع فئات حسب خطورتها من حيث كيفية استخدامها ومدى تأثيرها على مستخدميها على النحو التالي:

الفئة (أ): الأجهزة التشخيصية منخفضة المخاطر على الفرد والصحة العامة وتشمل الأجهزة والمستلزمات المخبرية العامة مثل الأدوات والمحاليل المستخدمة خلال عملية الكشف والقياس وأوعية جمع العينات كما هو مذكور في الملحق المرفق بهذا القرار.

الفئة (ب): الأجهزة التشخيصية منخفضة إلى متوسطة المخاطر على الفرد والصحة العامة، وتشمل فحوصات التقييم الذاتي العامة أو غيرها من الفحوصات منخفضة المخاطر مثل أجهزة فحص الحمل الذاتي وشرائط فحص البول كما هو مذكور في الملحق المرفق بهذا القرار.

الفئة (ج): الأجهزة التشخيصية متوسطة إلى عالية المخاطر على الفرد والصحة العامة والتي تتطلب دقة عالية نظرا لتأثيرها على القرارات الطبية مثل الكواشف المستخدمة للكشف عن الأمراض المنقولة جنسياً كالسيلان وأجهزة فحص السكر الذاتي في الدم كما هو مذكور في الملحق المرفق بهذا القرار.

الفئة (د): الفحوصات المخبرية عالية المخاطر التي تستخدم للكشف عن الأمراض المعدية شديدة الخطورة على الفرد والصحة العامة مثل الكواشف المستخدمة للكشف عن الأمراض المعدية المنقولة عن طريق الدم أو مكونات الدم أو الأنسجة أو الأعضاء أو أي من مشتقاتهم مثل مرض الإيدز (نقص المناعة المكتسب)، والإلتهاب الكبدي الوبائي و(ب) فحوصات تحديد فصائل الدم المذكورة في الملحق المرفق بهذا القرار.

مادة رابعة:

يتضمن ملحق القرار باللغة الإنجليزية على تفصيل كامل للقواعد الأساسية المستخدمة لتصنيف الأجهزة والمستلزمات الطبية والأجهزة التشخيصية حسب درجة خطورتها مع الأمثلة، كما يتضمن الملحق كامل المتطلبات والشروط التي يجب توافرها في ملف تسجيل الأجهزة والمستلزمات الطبية والأجهزة التشخيصية وفقاً للمسارات التنظيمية المذكورة في هذا القرار.

مادة خامسة:

تخضع للتسجيل جميع الأجهزة والمستلزمات الطبية المراد تسويقها في دولة الكويت وفقاً لهذا القرار.

مادة سادسة:

يشترط لتسجيل الأجهزة والمستلزمات الطبية تقديم الممثل المعتمد للشركة صاحبة حق التسويق طلب تسجيل موجه إلى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية طبقاً للشروط والمتطلبات التالية:

1. المتطلبات الخاصة بالوكيل المحلي:

1.1 ترخيص مزاولة نشاط استيراد الأدوية والمستلزمات الطبية أو ما يعادله صادر من وزارة التجارة والصناعة.

1.2 ترخيص الشركة لاستيراد الأدوية والمستلزمات الطبية صادر من وزارة الصحة.

1.3 ترخيص مستودع صادر من وزارة الصحة.

1.4 تفويض توقيع ممثلي الشركة صادر من غرفة التجارة والصناعة.

1.5 صور عن البطاقة المدنية لممثلي الشركة.

2. المتطلبات الخاصة بالمكتب العلمي أو فرع الشركة صاحبة حق التسويق:

2.1 ترخيص مزاولة نشاط مكتب علمي أو فرع للشركة صاحبة حق التسويق صادر من وزارة التجارة والصناعة.

2.2 ترخيص مكتب علمي أو فرع للشركة صاحبة حق التسويق صادر من وزارة الصحة.

2.3 تفويض توقيع ممثلي الشركة صادر من غرفة التجارة والصناعة.

2.4 صور عن البطاقة المدنية لممثلي الشركة.

3. المتطلبات الخاصة بالشركة صاحبة حق التسويق والشركة المصنعة في حال اختلافها عن الشركة صاحبة حق التسويق:

3.1 خطاب الوكالة يوضح العلاقة التجارية بين الوكيل المحلي والشركة صاحبة حق التسويق أو المصنع القانوني، أو الموزع المعتمد إن وجد من تأكيد الشركة المالكة لحقوق التسويق على العلاقة بينها وبين الموزع المعتمد[1].

3.2 شهادة توضح العلاقة بين الشركة المصنعة والشركة صاحبة حق التسويق صادرة من الأخيرة.

3.3 شهادة ترخيص الشركة المصنعة صادرة من السلطات الصحية أو الرقابية في بلد المنشأ[1].

3.4 شهادة تطبيق أسس التصنيع الجيد للشركة المصنعة صادرة من السلطات الصحية أو الرقابية في بلد المنشأ أو شهادة مطابقة المعايير الدولية للجودة (ISO) ذات الصلة بتصنيع المنتج.

3.5 تقديم ملف تسجيل لجهاز أو مستلزم طبي واحد أو أكثر.

3.6 طرق التواصل مع الشركة يشمل أرقام الهواتف والبريد الإلكتروني أو أي طرق تواصل أخرى.

● يتوجب تقديم أصول هذه الشهادات وتصديقها كما هو موضح في المادة الثامنة من هذا القرار.

ملاحظات: يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية القيام بزيارة الشركة المصنعة للتأكد من تطبيق أسس التصنيع الجيد متى ما ارتأت ذلك، وفقاً للشروط والضوابط المعتمدة.

4. المتطلبات الخاصة بتسجيل الأجهزة والمستلزمات الطبية:

– يشترط أن يكون الجهاز او المستلزم الطبي المقدم للتسجيل مسجل ومسوق في بلد المنشأ، وفي حال عدم تسويقه يتم توضيح الأسباب، ومن ثم تدرس من قبل إدارة تسجيل ورقابة الأدوية والمنتجات الطبية للموافقة أو رفض طلب التسجيل.

مادة سابعة:

يتضمن ملحق القرار باللغة الإنجليزية كامل المتطلبات التي يجب توافرها في ملف تسجيل الأجهزة والمستلزمات الطبية حسب درجة خطورتها من الفئات الأربع السابق ذكرها.

مادة ثامنة:

يُعتمد التحقق الإلكتروني Electronic Verification للشهادات إن وجد دون الحاجة إلى التصديق الورقي من الجهات المعنية وفق الشروط التالية:

1. في حال عدم وجود التحقق الإلكتروني يتوجب على الشركات تصديق الشهادات من سفارة/ قنصلية دولة الكويت من بلد المنشأ أو في سفارة / قنصلية خليجية في حال عدم وجود سفارة لدولة الكويت في بلد المنشأ.

2. يتوجب تصديق شهادة الوكالة بين الوكيل المحلي والشركة صاحبة حق التسويق للمستحضرات الصحية أو شهادة إلغاء الوكالة من سفارة / قنصلية دولة الكويت من بلد المنشأ أو في سفارة/ قنصلية خليجية في حال عدم وجود سفارة لدولة الكويت في بلد المنشأ بالإضافة إلى غرفة التجارة في بلد المنشأ.

مادة تاسعة:

تعتمد المسارات التالية لتسجيل الأجهزة والمستلزمات الطبية في إدارة تسجيل ورقابة الأدوية والمنتجات الطبية وعددها 3 مسارات:

1. المسار القياسي (Standard Pathway): تقييم علمي شامل للملف المقدم لتسجيل الأجهزة والمستلزمات الطبية وفقاً للمتطلبات المذكورة في ملحق القرار الوزاري المنظم باللغة الإنجليزية.

2. المسار السريع (Fast Track Pathway): يطبق مسار المراجعة السريع على الأجهزة والمستلزمات الطبية والأجهزة التشخيصية المخبرية وفقاً لمعايير محددة بعد تقديم طلب الممثل المعتمد لإدراج المنتج في المسار السريع موضحا به مبررات الطلب، على أن يستوفي الطلب إحدى الشروط التالية:

2.1 طلب مقدم من إدارة المستودعات الطبية موجه إلى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية أو عقد توريد ساري الصلاحية.

2.2 أن يغطي الجهاز حاجة طبية أساسية، مثل:

– الأجهزة والمستلزمات الطبية المطلوبة للعمليات الجراحية الخطيرة.

– الأجهزة والمستلزمات الطبية المخصصة للاستخدام في وحدات العناية المركزة (ICUs).

2.3 أن يكون الجهاز أو المستلزم الطبي مخصصاً لعلاج أو تشخيص أو إدارة حالات خطيرة أو مهددة للحياة، أو لعلاج حالة طبية غير ملباة، في حال عد توفر بديل مسجل في دولة الكويت.

3. المسار المختصر Abridged Pathway)):

تقييم معجل للأجهزة الطبية من خلال الاعتماد التنظيمي على سلطات مرجعية صارمة معتمدة، بالإضافة إلى تقييم المتطلبات الرقابية المحلية، ومتطلبات الرقابة مابعد التسويق.

ملاحظة: يتم اتخاذ القرار النهائي بشأن قبول الطلب بموجب المسار السريع أو المسار المختصر من قبل إدارة تسجيل ورقابة الأدوية والمنتجات الطبية، وذلك بعد إجراء تقييم شامل للطلب المقدم والمستندات الداعمة له.

مادة عاشرة:

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية طلب أي مستندات أو دراسات إضافية أو طلب عينات لإجراء تحاليل مخبرية في مختبرات الإدارة أثناء أو بعد عملية التسجيل وعلى الشركة الالتزام بذلك.

مادة حادية عشر:

يجب على الشركة صاحبة حق التسويق/ المصنع القانوني المعتمد لدى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية إخطارها بأي تغيير أو تعديل يطرأ على المنتج على ألا يتم تطبيق هذا التغيير داخل دولة الكويت إلا بعد الحصول على موافقة الإدارة على ذلك.

مادة ثانية عشر:

صلاحية شهادة تسجيل الجهاز أو المستلزم الطبي خمس سنوات من تاريخ الإصدار.

مادة ثالثة عشر:

الأجهزة والمستلزمات الطبية المصنعة محلياً أو حق تسويقها مملوك لصالح شركة محلية فإن إصدار شهادات هذه المنتجات وشهادة تسجيل للشركة المصنعة أو صاحبة حق التسويق وشهادة أسس التصنيع الجيد وغيرها من الشهادات المتعلقة بها يكون من اختصاص إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.

مادة رابعة عشر:

يجب إعادة تجديد تسجيل الجهاز أو المستلزم الطبي والشركة المصنعة، على أن يقدم الوكيل المحلي طلباً تجديد التسجيل والمستندات المطلوبة من قبل الإدارة قبل ستة أشهر من إنتهاء مدة صلاحية شهادة التسجيل.

مادة خامسة عشر: يجب عند نقل وكالة الشركة صاحبة حق التسويق من وكيل محلي إلى آخر تقديم المستندات التالية:

1. شهادة الوكالة صادرة من الشركة صاحبة حق التسويق/ المصنع القانوني المعتمد لدى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية (أو الموزع المعتمد مع تقديم الشركة صاحبة حق التسويق ما يثبت وجود علاقة تجارية سارية مع الموزع المعتمد) بتعيين وكيل محلي جديد لها مرخص من قبل وزارة التجارة ووزارة الصحة.[1]

2. شهادة إلغاء الوكالة الممنوحة للوكيل السابق من الشركة صاحبة حق التسويق/ المصنع القانوني المعتمد لدى إدارة تسجيل ورقابة الأدوية والمنتجات الطبية (أو الموزع المعتمد مع تقديم الشركة صاحبة حق التسويق ما يثبت وجود علاقة تجارية سارية مع الموزع المعتمد) موضحاً بها تاريخ إلغاء الوكالة.[1]

3. قائمة بالأجهزة والمستلزمات الطبية الخاضعة لنقل الوكالة صادرة من الشركة صاحبة حق التسويق موضحاً فيها الاسم التجاري للمستحضر، التركيز، الشكل الصيدلاني، والشركة المصنعة.

• [1] يتوجب تقديم أصول هذه الشهادات وتصديقها كما هو وارد في المادة الثامنة من هذا القرار.

مادة سادسة عشر:

يجب على مقدم طلب التسجيل (الممثل المعتمد) إبلاغ إدارة تسجيل ورقابة الأدوية والمنتجات الطبية بوزارة الصحة في حالة صدور أي تحذير من أي من الجهات الرقابية الدولية بشأن سلامة ومأمونية استخدام الجهاز أو المستلزم الطبي.

مادة سابعة عشر:

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية تعليق تسجيل أي جهاز أو مستلزم طبي أو شركة صاحبة لحق التسويق / الشركة المصنعة إذا ثبت للإدارة ما يلي:

1. إذا صدر قرار بتعليق أو حظر الجهاز أو المستلزم الطبي أو الشركة من قبل السلطات الرقابية في بلد المنشأ.
2. إذا ثبت عدم فعالية ومأمونية استخدام الجهاز أو المستلزم الطبي.
3. إذا ثبت التلاعب في المستندات المقدمة لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية.
4. إذا ثبت مخالفة الشركة لنظم ولوائح إدارة تسجيل ورقابة الأدوية والمنتجات الطبية.
5. إذا ثبت عدم استمرار الشركة باتباع أسس التصنيع الجيد أو اسس مطابقة المعايير الدولية للجودة(ISO).
6. تكرار عدم إجتياز الجهاز أو المستلزم الطبي للتحليل لدى فحص الأدوية والمنتجات الطبية.
7. في حال عدم إبلاغ الوكيل المحلي لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية عن صدور أي تحذيرات تخص الجهاز أو المستلزم الطبي أو الشركة من الهيئة الصحية المعتمدة.

مادة ثامنة عشر: يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية إلغاء تسجيل أي جهاز أو مستلزم الطبي صحي أو شركة مالكة لحق التسويق/ الشركة المصنعة وذلك إذا ثبت للإدارة ما يلي:

1. إذا تم إلغاء تسجيل الجهاز أو المستلزم الطبي أو الشركة في بلد المنشأ.
2. عدم مطابقة الجهاز أو المستلزم الطبي للمواصفات الفنية المعتمدة بملف التسجيل لدى الإدارة.
3. بناءً على طلب الشركة صاحبة حق التسويق مع ذكر الأسباب.
4. إذا ثبت عدم فعالية وأمان استخدام الجهاز أو المستلزم الطبي.
5. عدم تجديد التسجيل في الفترة المحددة.
6. إذا ثبت التزوير في المستندات المقدمة لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية.
7. إذا مضت سنتان من دون استيراد الجهاز أو المستلزم الطبي إلى دولة الكويت.
8. عدم تقديم الشركة المبررات والمستندات الداعمة لإلغاء تعليق الجهاز أو المستلزم الطبي خلال ست شهور من التعليق.
9. إذا ثبت احتواء المنتج على مادة فعالة غير معلن عنها.

10. تكرار عدم اجتياز الجهاز أو المستلزم الطبي للتحليل لدى مختبرات إدارة تسجيل ورقابة الأدوية والمنتجات الطبية بحد أقصى 5 مرات.

مادة تاسعة عشر:

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية رفض تسجيل أي جهاز أو مستلزم الطبي أو شركة دوائية مع ذكر الأسباب التي أدت إلى رفض طلب التسجيل.

مادة عشرون:

يحق للوكيل المحلي الإعتراض على قرار الإدارة في رفض التسجيل أو تعليق التسجيل أو إلغائه خلال مدة أقصاها 90 يوما من تاريخ صدور القرار، وعليه يعتبر القرار نهائيا بعد تقديم الرد بناءً على دراسة الاعتراض.

مادة حادية وعشرون:

يحق لإدارة تسجيل ورقابة الأدوية والمنتجات الطبية في حال عدم إلتزام الشركة بتوريد الأجهزة والمستلزمات الطبية أو عدم الإلتزام بالشروط والضوابط المذكورة في هذا القرار إلغاء التسجيل أو الموافقة على تعيين وكيل محلي آخر في دولة الكويت.

مادة ثانية وعشرون:

يخضع الإفراج عن الأجهزة والمستلزمات الطبية والسماح بتداولها للقرارات الوزارية المنظمة لذلك.

مادة ثلاثة وعشرون:

لا يتم الإعلان عن الأجهزة والمستلزمات الطبية إلا بعد الحصول على الموافقات الخاصة من الإدارة المعنية في وزارة الصحة.

مادة رابعة وعشرون:

تسجيل الأجهزة والمستلزمات الطبية يخضع للرسوم المقررة في القرار الوزاري المنظم لأسعار وأجور الخدمات الصحية.

مادة خامسة وعشرون:

يُبلغ هذا القرار من يلزم لتنفيذه، ويعمل به إعتباراً من تاريخ صدور القرار، ويلغى كل قرار أو نص يتعارض مع أحكام هذا القرار وينشر في الجريدة الرسمية.

وزير الصحة

د. أحمد عبدالوهاب العوضي

صدر في: 10 رجب 1447هـ

الموافق: 30 ديسمبر 2025م

MINISTERIAL DECREE FOR REGISTRATION OF MEDICAL DEVICES & IVD DEVICES

ملحق القرار الوزاري رقم (387) لسنة 2025

بشأن تسجيل و تداول الأجهزة والمستلزمات الطبية

(2025/387) M.D

Version 1.0

December 2025

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following specific medical purposes:
diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices: — devices for the control or support of conception; products specifically intended for the cleaning, disinfection or sterilization of devices

What is an IVD Device

In vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
concerning a physiological or pathological process or state;
a. concerning congenital physical or mental impairments;
b. concerning the predisposition to a medical condition or a disease;
c. to determine the safety and compatibility with potential recipients;
d. to predict treatment response or reactions;
e. to define or monitoring therapeutic measures.
Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

Other Related Terms Definitions

Accessory to a medical device: Means an article intended specifically by its manufacturer to be used together a particular medical device to enable or assist that device to be used in accordance with its intended use.
Active medical device: Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Standalone software is considered to be an active medical device.

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Medical devices are required to be registered in order to comply with applicable regulatory requirements, which aims to ensure that all medical devices placed on the market meet established standards of safety, quality, and performance.
This guideline is intended to assist applicants in understanding the medical device classification criteria prior to importation or submission for registration. The classification rules and requirements outlined herein are used to determine the risk level of a product, as well as to establish whether the product falls within the definition of a medical device.
Applicants are strongly encouraged to be informed about themselves with the classification principles, regulatory requirements, and review processes described in this guideline before submitting an application, in order to facilitate an efficient and compliant regulatory assessment.

Purpose

The purpose of this guidance is to describe the procedures and general requirements for the submission of medical device & IVD Device dossier.

Scope

This guidance applies to the following products:
- Medical Devices
- IVD devices

Definition

What is a Medical Device

Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the

Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.
Implantable device: Any device, including those that are partially or wholly absorbed, which is intended:
to be totally introduced into the human body or,
to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure.
Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.
Intended use / Intended purpose: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.
Invasive devices: A device, which in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
ISO 13485: Is the internationally recognized standard for quality management systems in the design and manufacture of medical devices. It outlines specific requirements that help organizations ensure their medical devices meet both customer and regulatory demands for safety and efficacy.
Legal manufacturer/ Marketing authorization Holder (MAH): means the natural or legal entity with responsibility for the design, manufacture, packaging and labeling of a device to be market under his own name.
Medical device gases: Medical devices that contain or rely on gases whose intended purpose is achieved solely through a physical mode of action and the gas does not exert any therapeutic, pharmacological, immunological, or metabolic effect on the human body. Such gases are classified as medical device supplies under the Kuwait Medicine and Medical Products Registration and Regulatory Administration. Example: Gases used for applications such as cryotherapy, where the primary function is tissue cooling or freezing through a physical mechanism, fall within this category. In these cases, the gas is considered an integral component, accessory, or consumable supply of the medical device. The regulatory classification is determined based on the manufacturer's intended purpose and the principal mode of action.
Performance: The ability of a medical device to achieve its intended purpose as stated by the manufacturer, performance may include both clinical and technical aspects.
physical manufacturer: in relation to a medical device, means any site who performs any manufacturing activities of medical device
post-market surveillance: all activities carried out by

Active therapeutic device: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness or injury.
Authorized Representative: also referred to as the Local Agent or scientific office or local approved affiliates, is a legal entity established in the State of Kuwait, officially appointed by the Marketing Authorization Holder (MAH)/ Legal Manufacturer to act on their behalf before the Medicine and Medical Products Registration and Regulatory Administration in all matters related to the registration, importation, pricing, post-marketing surveillance, and communication of medicinal products.
Body Orifice: A natural opening or a permanent artificial opening in the body, such as a stoma.
CE marking: means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in European regulation.
Central Medical Store (CMS): Kuwait Entity for Drug/ Devices Procurement for the Public Sector
Cleaning: Removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.
Clinical evaluation: A systematic and planned process to continuously generate, collect, analyses and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.
Disinfection: Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.
Duration of Use
Short term: Normally intended for continuous use for between 60 minutes and 30 days.
Transient: Normally intended for continuous use for less than 60 minutes.
Long term: Normally intended for continuous use for more than 30 days.
Effectiveness: A device is clinically effective when it produces the effect intended by the manufacturer relative to the medical conditions.
Essential principle: This document applies to all medical devices and IVD medical devices and is intended to identify and describe essential principles of safety and performance which should be considered during the design and manufacturing process. Depending on the particular medical device or IVD medical device, some of the essential principles of safety and performance apply as per IMDRF guidelines.
IMDRF: a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global

through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

Authorized Representative Registration/ Local authorized agent

If the authorised representative is a new local medical device supplies company, the following must be submitted:

- Valid license issued by the Ministry of Commerce in which the company activity includes the sale of medicines.
- Valid agency license issued by Pharmaceutical Inspection & Licensing Administration.
- Valid store license issued by Pharmaceutical Inspection & Licensing Administration.
- Copy of authorized signatories from public authority of manpower.
- Copy of authorized personal legalized from Kuwait chamber of commerce.
- Any other documents set by the administration in accordance with other MD's or memos issued.

Review Application Pathways

Kuwait Medicine and Medical Products Registration and Regulatory Administration accepts three types of review applications in accordance with the applicable Regulatory Frameworks. The following review pathways are generally applicable for the registration of medical devices and in vitro diagnostic (IVD) devices:

- Standard Review pathway
- Fast-Track Review pathway
- Abridged Review Pathway

Standard Review Pathway

Applications submitted under the Standard Review Pathway shall undergo a full regulatory assessment in accordance with the applicable requirements, timelines, and procedures defined by Kuwait Medicine and Medical Products Registration and Regulatory Administration

Fast-Track Pathway

The Fast-Track Review Pathway may be considered for medical devices or IVDs that meet specific eligibility criteria, subject to regulatory approval.

6.2.1 Requirement for Fast-Track Pathway

A. Submission of a formal request for Fast-Track review.

B. Condition for Fast-Track Review.

- At least one (1) of the following conditions shall apply:

i. A request from the Central Medical Stores (CMS), or a valid CMS supply contract.

ii. The device is met an essential medical supply need.

- Devices required for Critical surgical procedures;
- Devices intended for use in Intensive Care Units (ICUs)

iii. The device is intended for the treatment, diagnosis, or management of serious or life-threatening conditions, or addresses an unmet medical need, where no suitable registered alternative is available in the State of Kuwait.

C. Documentation Requirements for Fast-track Review pathway

manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

Reusable medical device: Means a device intended for repeated use either on the same or different patients, with appropriate decontamination and other reprocessing between uses.

Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilization have been carried out.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

Software: Medical device software (MDSW) is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the medical devices regulation or in vitro diagnostic medical devices regulation. Software which drives a device or influences the use of the device shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right

STED: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices. (STED) as per IMDRF guidelines

Sterilization: Validated process used to render product free from viable microorganisms.

Substance-base medical device:(medical device in pharmaceutical form): substance-based medical devices are composed of substances or combinations of substances (example: saline sprays, Lubricating eye drops) that achieve their primary medical effect through physicochemical or physical means, not pharmacological, metabolic, or immunological actions, though they can contain ancillary medicinal substances.

Surgically invasive device:

An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

A medical device which produces penetration other than through a body orifice.

System: means a combination of products, either packaged together or not, which are intended to be inter- connected or combined to achieve a specific medical purpose.

Unique Device Identifier (UDI): Means a series of numeric or alphanumeric characters that is created

Kuwait in the country of origin.

In cases where this is not possible, legalization may be done by an authorized GCC Embassy or Consulate in the country of origin.

Other Official Documents such as the Letter of Appointment, similar administrative documents must be legalized by the Embassy or Consulate of the State of Kuwait in the country of origin (or an authorized GCC Embassy/Consulate if not available), and The Chamber of Commerce in the country of origin.

Electronic Certificates and Electronic Verification

Valid Electronic certificates are acceptable provided that an approved verification tool is available for the authentication and verification of the electronic certificates, with no need for paper legalisation.

Electronic legalization is acceptable provide that an approved verification tool is available for the authenticity of legalisation.

Classification System for Medical Devices:

Structure of the Classification Rules

a. Classification system consisting of four classes where Class A represents the lowest hazard and Class D the highest.

b. The determination of class should be based on rules derived from the potential of a medical device to cause harm to a patient or user (i.e. the hazard it presents) and thereby on its intended use and the technologies it utilizes.

c. The manufacturer should document its justification for placing its product into a particular class.

d. it is based on the manufacturer intended use, two or more classification rules apply to the device, the device is allocated the highest level of classification indicated.

e. Where one or more medical device is intended to be used together with a different medical device, that may or may not be from the same manufacturer, (e.g. a pulse oximeter and a replaceable sensor sourced from a different manufacturer, or a general-purpose syringe and a syringe driver), the classification rules should apply separately to each of the devices.

f. Classification of an assemblage of medical devices where one or more of the medical devices that is in the assemblage has yet to comply with all the relevant regulatory requirements, should be for the combination as a whole according to its intended use.

g. While most software is incorporated into the medical device itself, some is not. Provided such standalone software falls within the scope of the definition for a medical device

Diagrammatic Representation of the Classification System

1. The device shall be approved and registered by at least one (1) of the following reference international regulatory authorities:

- United States: U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH)
- Australia: Therapeutic Goods Administration (TGA)
- Brazil: Brazilian Health Regulatory Agency (ANVISA)
- Canada: Health Canada (HC)
- Japan: Ministry of Health, Labour and Welfare (MHLW) and/or Pharmaceuticals and Medical Devices Agency (PMDA)
- United Kingdom: Medicines and Healthcare products Regulatory Agency (MHRA), with valid UKCA approval
- Approved in any European union county with valid CE certificate

2. Applicants shall submit required documentation in accordance with the Kuwait Medicine and Medical Products Registration and Regulatory Administration requirements, as specified in the Document Requirements Section, 12 for Medical Device & Document Requirements Section 16 for IVD corresponding to risk class.

Abridged Review Pathway

A reliance based regulatory pathway that enables accelerated assessment of Medical device/ IVD device by leveraging approval form recognized reference authorities (e.g., FDA, EU Union country approval with CE certificate, Health Canada, Japan PMDA, UK MHRA, Brazil ANVISA, TGA Australia) combined with national regulatory requirement and post market requirements are subject to assessment under the Abridged Review pathway.

Condition for Abridged Pathway:

The product shall be identical in design, intended use, and manufacturing site to the product approved by one or more recognized reference regulatory authorities. No differences in product specifications, materials, formulation, performance, or manufacturing processes shall be permitted compared to the reference-approved product.

Final Determination for Fast-Track & Abridged Review pathway application

The final decision regarding acceptance of an application under the Fast-Track Review Pathway & Abridged review pathway shall be made solely by the Kuwait Medicine and Medical Products Registration and Regulatory Administration, following a comprehensive regulatory assessment of the submitted application and supporting documentation.

Document Legalization and Certification

Legalization of Certificates issued by Regulatory Authorities such as the Free Sale , GMP Certificate, & ISO certificate from the Notified Body must be Original, legalized by the Embassy or Consulate of the State of

Medical devices compromising a procedure pack may be bundled/grouped within one application only if they:

- Same legal manufacturer
- Same intended use/purpose and under the same specialty.

Submission requirements: For the procedure pack: applicant shall submit technical documents (Device Description) for each component.

Note: Total Number of medical device that are grouped/bundled within a single application shall not exceed 50 items.

IVD Medical Devices

Note: If the device has accessories, they may be included with the device within the same application, unless they are marketed separately.

9.2.1. IVD Devices

IVD Devices pack be bundled/grouped within a one application only if they:

- Same Risk class.
- Same legal manufacture.
- Same intended use/Same principle of operation
- Same specialty [submitted IVD fall under any one Lab specialty hematology, microbiology, serology, biochemistry, histology]

Note: Total Number of IVD medical device that are grouped/bundled within a single application shall not exceed 50 items.

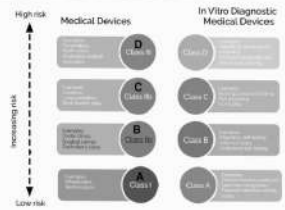
Note: The acceptability of device bundling or grouping within a single application shall be subject to case–by–case assessment. The final decision regarding the approval, modification, or rejection of such bundling or grouping shall rest solely with the Kuwait Medicine and Medical Products Registration and Regulatory Administration, following a comprehensive evaluation of the submitted documentation, product characteristics, intended use, and applicable regulatory requirements.

The Technical Documents framework for Medical Devices & IVD devices

The Kuwait Medicine and Medical Products Registration and Regulatory Administration shall adopt the Essential Principles checklist and the Summary Technical Documentation (STED) as part of the Regulation on Registration of Medical Devices & IVD devices, in alignment with the principles established by the International Medical Device Regulators Forum (IMDRF), with the objective of promoting regulatory convergence and harmonization with internationally recognized laws and regulatory requirements.

This adoption aims to ensure that medical devices placed on the market meet the applicable requirements for safety, quality, and performance, while supporting medical device manufacturers and authorized representatives in enhancing their global regulatory compliance and international competitiveness.

In consideration of the wide range and diversity of medical



Proposed general classification system for Medical Devices & IVD Devices

Class	Risk Level
A	Low risk
B	Low–moderate Risk
C	Moderate–high Risk
D	High Risk

Bundling Criteria for Medical devices & IVD Devices

Medical devices may be bundled/grouped within one application based on the criteria of each category below:

Medical Devices

a. Medical Devices Family

b. Medical Devices System

c. Medical Devices Procedure Pack

9.1.a. Medical Devices Family

A maximum of 5 groups of Medical devices may be bundled/grouped within one application only if they have:

- same legal manufacturer,
- same intended use/purpose,
- same risk class,
- same GMDN code (optional), and
- has a common physical design, construction material and manufacturing process.

Note: Total Number of medical device that are grouped/bundled within a single application shall not exceed 50 items.

9.1.b. Medical Devices System

Medical devices compromising a system may be bundled within one application only if they:

- Have same legal manufacturer
- Are intended to be used in combination to complete a common intended use/purpose.
- Are sold under a medical devices system name; or the labeling, instruction for use (IFU), brochures or catalogues for each constituent component states that the constituent component is intended for use/purpose with the system.

Note:

- that only one system per application.
- If the items of the system have different risk–classes, the highest risk–class will be considered.

Note: Total Number of medical device that are grouped/bundled within a single application shall not exceed 50 items.

9.1.c. Medical Devices Procedure Pack

	liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class B – if they may be connected to a class B, class C or class D active device; or if they are intended for use for channeling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues.	● Devices used for channelling gases, e.g. antistatic tubing for anaesthesia, anaesthesia breathing circuits ● Syringes for infusion pumps ● Devices intended to channel blood (e.g. in transfusion, extracorporeal circulation) ● Devices intended for temporary storage and transport of organs for transplantation (i.e. containers, bags) ● Devices intended for long term storage of biological substances and tissues such as corneas, sperm, human embryos, etc. (i.e. containers, bags) ● Fridges/freezers specifically intended for storing blood, tissues etc. ● Tubings/blood lines for extracorporeal treatment (dialysis and apheresis therapies)
C	except for blood bags; blood bags are classified as class C.	● Blood bags without a substance which, if used separately, can be considered to be a medicinal product
A	In all other cases, such devices are classified as class A	● Non–invasive devices that provide a simple channelling function, with gravity providing the force to transport the liquid, e.g. administration sets for infusion. ● Devices intended to be used for a temporary containment or storage function, e.g. cups and spoons specifically intended for administering medicines2 Empty syringes without needles

Rule 3: Devices that modify biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body

Class	Rule 3	Examples
C	All non–invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class C	● Devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodialysers ● Devices intended to separate cells by physical means, e.g. gradient medium for sperm separation ● Haemodialysis concentrates ● Device removing specific blood cells (e.g. activated) by specific binding to a matrix.
B	unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class B	● Particulate filtration of blood in an extracorporeal circulation system. These are used to remove particles from the blood ● Centrifugation of blood to prepare it for transfusion or autotransfusion excluding centrifuges for manufacturing a medicinal product ● Removal of carbon dioxide

device & IVD Devices, Kuwait Medicine and Medical Products Registration and Regulatory Administration may require medical device entities to submit appropriate technical documentation, including STED, for regulatory review, in order to demonstrate conformity with the Essential Principles and to substantiate the safety and performance of the medical devices.

Medical Devices Rules & Requirements

Classification Rules for Medical Devices

The actual classification of each device depends on the claims made by the manufacturer for its intended use and the technologies it utilizes. As an aid to interpreting the purpose of each rule, illustrative examples of medical devices that should conform to the rule have been provided in the table below. However, it must be emphasized that a manufacturer of such a device should not rely on it appearing as an example but should instead make an independent decision on classification taking account of its particular design and intended use.

General explanation of Medical Device rule with examples

Non–Invasive Devices

Rule 1 –Devices that either do not come in direct contact with the patient or contact intact skin only

Class	Rule 1	Examples
A	All non–invasive devices are classified as class I, unless one of the rules set out hereinafter applies	● Devices intended in general for external patient support (e.g.hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chairs); ● Body liquid collection devices intended to be used in such a way that a return flow is unlikely (e.g. to collect body wastes such as urine collection bottles, incontinence pads or collectors used with wound drainage devices). They may be connected to the patient by means of catheters and tubing ● Devices used to immobilise body parts and/or to apply force or compression on them (e.g.non–sterile dressings used to aid the healing of a sprain, plaster of Paris, cervical collars, gravity traction devices, compression hosiery) ● Stethoscopes ● Eye occlusion plasters ● Incision drapes ● Non–invasive conductive gels i.e. ultrasound gels2 ● Non–invasive electrodes (electrodes for EEG or ECG) ● Permanent magnets for removal of ocular debris ● Wheel chair pushed by hand

Rule 2 – Channeling or storing for eventual administration

Class	Rule 2	Examples
B	All non–invasive devices intended for channeling or storing blood, body liquids, cells or tissues,	● Devices intended to be used as channels in active drug delivery systems, e.g. tubing intended for use with an infusion

	invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: class I if they are intended for transient use;	● Dental impression materials ● Stomach tubes ● Impression trays ● Examination gloves ● Urinary catheters intended for transient use ● Embryo transfer catheter and insemination catheter
B	class B if they are intended for short-term use.	● Short term corrective contact lenses ● Tracheal tubes ● Indwelling urinary catheters intended for short term use ● Gauses used for insufflation in the body ● Nasobilliary tubes
A	except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class A; and	● Materials for dental impressions ● Plastic syringe used to measure a quantity of medicinal product before oral administration to the patient ● Removable or fixed dental prostheses
C	class C if they are intended for long-term use.	● Urethral stents ● Long term corrective contact lenses ● Tracheal cannulae for tracheostoma for long term use ● Urinary catheters intended for long term use
B	except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class B.	● Orthodontic wires ● Fixed dental prostheses ● Fissure sealants
B	All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class B, class C or class D active device, are classified as class B	● Tracheostomy or tracheal tubes connected to a ventilator ● Blood oxygen analysees placed under the eye-lid ● Powered nasal irrigators ● Fibre optics in endoscopes connected to surgical lasers ● Suction catheters or tubes for stomach drainage ● Dental aspirator tips ● Endoscopes using a light source in the visible spectrum

Rule 6 – Surgically invasive devices intended for transient use (<60 min)

Class	Rule 6	Examples
B	All surgically invasive devices intended for transient use are classified as class B	● Needles used for suturing ● Needles or syringes ● Lancets ● Single use scalpels and single use scalpel blades ● Surgical swabs ● Surgical gloves ● Swabs to sample exudates ● Guidewires or catheters used outside the central circulatory system

		from the blood and/or adding oxygen ● Warming or cooling the blood in an extracorporeal circulation system
D	All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class D.	● Substances or mixture of substances for transport, perfusion, storage of organs intended for transplantation that do not achieve the principal intended action by pharmacological, immunological or metabolic means ● IVF or ART products without principal pharmacological/metabolic action (substances or mixture of substances) ● IVF cell media without human albumin

Rule 4 – Devices that come into contact with injured skin or mucous membrane

Class	Rule 4	Examples
A	All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: – class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;	● Wound dressings for skin or mucous, such as absorbent pads, island dressings, cotton wool, wound strips, adhesive bandages (sticking plasters, band-aid) and gauze dressings which act as a barrier, maintain wound position or absorb exudates from the wound ● Ostomy bags
C	class C if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;	● Are principally intended to be used with severe wounds ● Dressings intended for ulcerated wounds having breached the dermis ● Dressings intended for burns having breached the dermis ● Dressings for severe decubitus wounds ● Dressings incorporating means of augmenting tissue and providing a temporary skin substitute
B	class B if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and	● Hydrogel dressings for wounds or injuries that have not breached the dermis or can only heal by secondary intent ● Non-medicated impregnated gauze dressings ● Polymer film dressings
A	This rule applies also to the invasive devices that come into contact with injured mucous membrane.	● Dressings for nose bleeds (the purpose of the dressing is not to manage micro-environment) are in class A according to this rule

Invasive Devices

Rule 5 – Devices invasive with respect to body orifices

Class	Rule 5	Examples
A	All invasive devices with respect to body orifices, other than surgically	● Handheld mirrors used in dentistry to aid in dental diagnosis and surgery

	- or	body, excluding the central circulatory system
C	have a biological effect or are wholly or mainly absorbed in which case they are classified as class C	● Viscoelastic solution for ophthalmic surgery
C	are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous4 taking account of the mode of application, in which case they are classified as class C	● Refillable insulin pens ● Analgesia pumps

Rule 7 – Surgically invasive devices intended for short-term use (> 60 min <30 days)

Class	Rule 7	Examples
B	All surgically invasive devices intended for short-term use are classified as class B unless they:	● Clamps ● Infusion cannulae ● Skin closure devices ● Temporary filling materials ● Arthroscopy trocars ● Insufflation gases for surgically invasive endoscopic procedures
D	are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class D	● Cardiovascular catheters ● Cardiac output probes ● Temporary pacemaker leads ● Thoracic catheters intended to drain the heart, including the pericardium ● Carotid artery shunts ● Ablation catheter ● Heart bypass cannula (aortic perfusion cannula and venous drainage cannula) ● Peripherally inserted central catheter (PICC) line and central line
D	are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class D	● Neurological catheters ● Cortical electrodes ● Central venous/vascular catheters
C	are intended to supply energy in the form of ionizing radiation in which case they are classified as class C	● Brachytherapy devices
D	have a biological effect or are wholly or mainly absorbed in which case they are classified as class D	● ● Absorbable sutures
C	are intended to undergo chemical change in the body in which case they are classified as class C , except if the devices are placed in the teeth; or	● Vascular closure devices ● Haemostatic foams
D	are intended specifically to control, diagnose, monitor or correct a defect2 of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class D	● Cardiovascular catheters (e.g. angioplasty balloon catheters, stent delivery catheters/systems), including related guidewires, related introducers and dedicated disposable cardiovascular surgical instruments e.g. electrophysiological catheters, electrodes for electrophysiological diagnosis and ablation. ● Catheters containing or incorporating sealed radioisotopes, where the radioactive isotope is not intended to be released into the body, if used in the central circulatory system ● Distal protection devices
A	are reusable surgical instruments, in which case they are classified as class A	● Scalpels and scalpel handles ● Reamers ● Drill bits ● Saws, that are not intended for connection to an active device ● Retractors, forceps, excavators and chisels ● Sternum retractors for transient use ● Staplers (outside the heart, central circulatory or central nervous system) ● Dental Osteotomes
D	are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class D	● Neuro-endoscopes ● Brain spatulas ● Direct stimulation cannulae ● Spinal cord retractors ● Spinal needles ● Cranium guide for use in craniotomy ● Dura mater protection; Bone punch for use on the cranium (Intended use: The dura mater protection is intended to protect the dura mator during surgical procedures. It has direct contact to the CNS. The bone punch can be used at the cranium. A direct contact to the CNS is possible during application.) ● Peripherally inserted central catheter (PICC) line ● Heart valve occluders, sizers and holders ● Cardiovascular drainage cannula specifically intended to circulate blood whilst located in the heart or central vascular system ● Cryo-ablation of the heart or spine ● Appliers/Forceps for aneurysm clips
C	are intended to supply energy in the form of ionising radiation in which case they are classified as class C;	● Catheters containing or incorporating sealed radioisotopes, where the radioactive isotope as such is not intended to be released into the

	are intended to administer medicinal products, in which case they are classified as class D	
D	are active implantable devices or their accessories, in which cases they are classified as class D	● Cochlear implants and accessories ● Implantable cardiac pacemakers ● Implantable cardioverter defibrillators (ICD): ● Leads, electrodes, adaptors for pacemakers and implantable defibrillators ● Implantable nerve stimulators ● Implantable bladder stimulators ● Implantable sphincter stimulators ● Accessories to active implantable devices (with or without contact to the heart), be it implantable or non-implantable active devices: ● torque wrench for implantable pulse generator / implantable cardioverter defibrillator ● cables for programmer / pacing system analyser ● magnet for implantable Pulse Generator / Implantable Cardioverter Generator ● programmer or an external transmitter intended for activating or controlling the implantable part of the device ● implantable pacemaker leads
D	are breast implants or surgical meshes, in which cases they are classified as class D	● Breast implants ● Breast tissue expanders ● Surgical meshes for hernia repair ● Tension-free vaginal tape
D	are total or partial joint replacements, in which case they are classified as class D , with the exception of ancillary components such as screws, wedges, plates and instruments; or	● Hip, knee ● Shoulder ● Ankle
D	are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class D with the exception of components such as screws, wedges, plates and instruments	● Spinal disc replacement implants ● Spinal implants: hooks that fix the rod on the spinal column ● Stems that are implantable in contact with the spinal column ● Device placed in the disc space ● Interbody fusion devices

Active devices

Rule 9 – Active therapeutic devices intended to administer or exchange energy, as well as active devices intended to control/monitor/directly influence certain devices

Class	Rule 9	Examples
B	All active therapeutic devices intended to administer or exchange energy are classified as class B	● Electrical and/or magnetic and electromagnetic energy: ● muscle stimulators ● external bone growth stimulators ● TENS devices ● eye electromagnets ● electrical acupuncture ● Thermal energy: ● heat exchangers, except the types described below ● Mechanical energy: ● powered dermatomes ● powered drills ● dental hand pieces ● Light: ● phototherapy for skin treatment and for neonatal care ● Sound: ● external hearing aids ● Ultrasound: ● equipment for physiotherapy ● Sleep apnoea ventilators without respirating function
C	unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class C	● Kinetic energy: ● lung ventilators ● Thermal energy: ● incubators for babies ● blood warmers ● electrically powered heat exchangers (with patients incapable of reacting, communicating /or who are without a sense of feeling) ● Electrical energy: ● high-frequency electrosurgical generators, and electrocautery equipment, including their electrodes ● external pacemakers and external defibrillators with no integrated or incorporated diagnostic function ● electroconvulsive therapy equipment ● Coherent light: ● surgical lasers ● Ultrasound: ● lithotriptors, surgical ultrasound devices ● high-intensity focused ultrasound (HIFU)
C	All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class C	● External feedback systems for active therapeutic devices
C	All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence	● Brachytherapy therapy devices if the device also generates the radiation ● Therapeutic cyclotrons and linear accelerators ● Therapeutic X-ray sources

C	are intended to administer medicines1, in which case they are classified as class C	● Temporal dialysis catheter, CVVH catheter

Rule 8 – Implantable devices and long-term surgically invasive devices (> 30 days)

Class	Rule 8	Examples
C	All implantable devices and long-term surgically invasive devices are classified as class C	● Artificial ligaments for reinforcement. Dental implants and abutments ● Shunts ● Peripheral stents and peripheral valves ● Plates ● Intra-ocular lenses ● Internal closure devices (including vascular closure devices) ● Tissue augmentation implants (excluding breasts) ● Peripheral vascular catheters for long-term use ● Peripheral vascular grafts and stents ● Penile implants ● Non-absorbable sutures, non-biodegreable bone cements and maxillo-facial implants, visco-elastic surgical devices intended specifically for ophthalmic anterior segment surgery ● Pedicle screws
B	are intended to be placed in the teeth, in which case they are classified as class B	● Bridges and crowns ● Dental filling materials and pins ● Dental alloys, ceramics and polymers
D	are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class D	● Prosthetic heart valves ● Aneurysm clips ● Vascular prosthesis and stents ● Central vascular catheters for long-term use ● Spinal stents ● CNS electrodes ● Cardiovascular sutures ● Permanent and retrievable vena cava filters ● Septal occlusion devices ● Intra-aortic balloon pumps ● External left ventricular assisting devices
D	have a biological effect or are wholly or mainly absorbed, in which case they are classified as class D	● Long term absorbable sutures ● Adhesives and implantable devices claimed to be bioactive through the attachment of surface coatings such as phosphoryl choline ● Biodegrable Bone Cements ● Elastoviscus fluids for joint enovementing hyaluronan of non-animal origin)
D	are intended to undergo chemical change in the body in which case they are classified as class D, except if the devices are placed in the teeth	● Rechargeable non-active drug delivery systems ● Peritoneal dialysis

	their performance, are classified as class C	
D	All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class D	● Programming units and pacing system analysers ● Cardioscopes with pacing pulse indicators specifically intended to monitor active implantable devices ● Programmer for: ● implantable Pulse Generator (IPG); ● implantable Cardioverter Defibrillator (ICD) ● implantable Loop Recorder ● Remote monitoring devices for active implantable devices

Rule 10 – Active devices for diagnosis and monitoring or intended for diagnostic or therapeutic radiology

Class	Rule 10	Examples
B	Active devices intended for diagnosis and monitoring are classified as class B – if they are intended to supply energy which will be absorbed by the human body,	● Magnetic resonance equipment ● Pulp testers ● Evoked response stimulators ● Diagnostic ultrasound
A	except for devices intended to illuminate1 the patient's body, in the visible spectrum, in which case they are classified as class A	● Examination lamps ● Surgical microscopes intended to illuminate the patient's body in the visible spectrum ● Dermatoscopes with integrated light sources
B	if they are intended to image in vivo distribution of radiopharmaceuticals; or	● Gamma cameras ● Positron emission tomography and single photon emission computer tomography
B	– if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	● Electrocardiographs ● Electroencephalographs ● Electronic thermometers ● Electronic stethoscopes ● Electronic blood pressure measuring equipment
C	unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class C	● Blood gas analysers used in open heart surgery ● Apnoea monitors, including apnoea monitors in home care ● Patient monitors (intended use: Monitor intended for multi-parameter patient monitoring. The device will produce visual and audible alarms if any of the physiological parameters monitored vary beyond pre-set limits and timed alarm recordings will be produced.), for example in intensive care monitoring, e.g. blood pressure, temperature, oxygen saturation
C	Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including	● Diagnostic X-Ray machine ● Computed Tomography Devices

	interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class C	

Rule 11 – Software intended to provide information to inform decisions with diagnosis or therapeutic purposes or software intended to monitor physiological processes.

Class	Rule 11	Examples
B	Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class B except if such decisions have an impact that may cause:	● MDSW intended to rank therapeutic suggestions for a health care professional based on patient history, imaging test results, and patient characteristics, for example, MDSW that lists and ranks all available chemotherapy options for BRCA-positive individuals. ● Cognitive therapy MDSW where a specialist determines the necessary cognitive therapy based on the outcome provided by the MDSW.
D	death or an irreversible deterioration of a person's state of health1, in which case it is in class D	● MDSW intended to perform diagnosis by means of image analysis for making treatment decisions in patients with acute stroke.
C	a serious deterioration of a person's state of health1 or a surgical intervention, in which case it is classified as class C	● A mobile app intended to analyse a user's heartbeat, detect abnormalities and inform a physician accordingly. ● MDSW intended for diagnosing depression based on a score resulting from inputted data on patient symptoms (e.g. anxiety, sleep patterns, stress etc.)
B	Software intended to monitor physiological processes is classified as class B	● MDSW intended to monitor physiological processes that are not considered to be vital. ● Devices intended to be used to obtain readings of vital physiological signals in routine check-ups including monitoring at home.
C	except if it is intended for monitoring of vital physiological parameters3, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class C	● Medical devices including MDSW intended to be used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care.
A	All other software is classified as class A	● MDSW app intended to support conception by calculating the user's fertility status based on a validated statistical algorithm. The user inputs health data including basal body temperature (BBT) and menstruation days to track and predict ovulation. The fertility status of the current day

		is reflected by one of three indicator lights: red (fertile), green (infertile) or yellow (learning phase/cycle fluctuation).

Rule 12 – Active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body

Class	Rule 12	Examples
B	All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class B	● Suction pump ● Feeding pumps ● Jet injectors for vaccination ● Elastomeric pumps or balloon pumps for infusion
C	unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class C	● Infusion pumps ● Ventilators ● Anaesthesia machines ● Anaestheticvaporisers ● Dialysis equipment ● Blood pumps for heart-lung machines ● Hyperbaric chambers ● Pressure regulators for medical gases ● Medical gas mixers ● Moisture exchangers in breathing circuits if used on unconscious or non-spontaneously breathing patients ● Oxygen concentrator used to deliver oxygen enriched air directly to the patient

Rule 13 – All other active devices

Class	Rule 13	Examples
A	All other active devices are classified as class A	● Electric wheelchairs ● Dental curing lights ● Electric hospital beds ● Patient hoists ● Dental patient chairs

Special rules

Rule 14 – Devices incorporating, as an integral part, an ancillary medicinal product, and medicinal products derived from human blood or blood plasma

Class	Rule 14	Examples
D	All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class D	● Bone cement with antibiotics ● Condoms with spermicide ● Catheters coated with anticoagulants (e.g. heparin) ● Endodontic materials with antibiotics ● Ophthalmic irrigation solutions principally intended for irrigation, which contain components supporting the metabolism of the endothelial cells of the cornea ● Dressings incorporating an antimicrobial agent where the agent has an ancillary action on the wound ● Drug eluting stents (e.g. coronary, pulmonary) ● Surgical sealants containing

		human serum albumin or thrombin ● Implants coated with human fibrinogen ● Blood bags incorporating heparin or other substances as anticoagulant agents which, if used separately, can be considered to be a medicinal product ● IVF cell media with human albumin2 ● Intra Uterine Devices (IUD) containing medicinal substances3 including copper or silver ● Catheter lubrication gels containing analgesia e.g. lidocaine

Rule 15 – Devices used for contraception or prevention of sexually transmitted diseases

Class	Rule 15	Examples
C	All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class C	● Condoms and femidoms (internal condoms) ● Contraceptive diaphragms ● Fertility monitors and medical device software intended to be used in contraception e.g. by using the basal body temperature)
D	unless they are implantable or long term invasive devices, in which case they are classified as class D	● Tubal ligation devices (e.g. clips or rings) ● Non-hormonal intrauterine contraceptive devices (IUCD or ICD)

Rule 16 – Specifically disinfecting, cleaning, rinsing, hydrating or sterilising devices

Class	Rule 16	Examples
C	All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class C	● Contact lens storing solutions ● Cleaners for contact lenses ● Ultraviolet, vibration, or ultrasonic devices for cleaning and disinfecting contact lenses
B	All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class B	● Disinfecting solutions specifically intended for non-invasive medical devices ● Washer–disinfectors intended specifically for disinfecting non-invasive medical devices ● Sterilisers intended to sterilise
C	unless they are disinfecting solutions or washer–disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing1, in which case they are classified as class C	● Solutions/disinfectors for trans oesophageal ultrasound probes) ● Washer–disinfector equipment specifically for disinfecting endoscopes or other invasive devices at the end point of processing (e.g. dental equipment) ● Disinfectants for the fluid pathways of haemodialysis equipment ● Denture disinfecting products

Rule 17 – Devices to record X–ray diagnostic images

Class	Rule 17	Examples
B	Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class B	● Digital x–ray detectors for recording images ● Photostimulable phosphor plates ● X–ray films

Rule 18 – Devices manufactured utilizing tissue or cells of human or animal origin or their derivatives

Class	Rule 18	Examples
D	All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives1, which are non- viable or rendered non–viable, are classified as class D	● Animal derived biological heart valves ● xenograft dressings ● Devices made from animal sourced collagen/gelatine ● Devices utilising hyaluronic acid of animal origin ● Substance–based devices containing collagen for use in body orifices ● Collagen dermal fillers ● Bone graft substitutes
A	unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non–viable or rendered non–viable and are devices intended to come into contact with intact skin only.	● Leather components of orthopaedic appliances

Rule 19 – Devices incorporating or consisting of nanomaterial

Class	Rule 19	Examples
	All devices incorporating or consisting of nanomaterial are classified as	
D	—class D if they present a high or medium potential for internal exposure	● Bone fillers with nanomaterials in their formulation (not polymerized before blood/tissue contact, and degradable) ● Superparamagnetic iron oxide nanoparticles (Intended use: thermal ablation of tumors or thermal modulation of the tumor microenvironment by submission to alternating magnetic fields) ● Intravascular catheter made of non-degradable polymer, with nano–coating
C	class C if they present a low potential for internal exposure	● Bone fixation screws/plates with a strongly bound nano-coating high potential ● Solution administration set made of non–degradable polymer, with a strongly bound nano–coating
B	class B if they present an eligible potential for internal exposure	● Intravascular catheter for short term use made of non-degradable polymer, with nanomaterial embedded in the polymer matrix ● Solution administration set

	pharynx1, and achieve their intended purpose on those cavities; and	● Oral cough treatments achieving their intended purpose in the oral cavity as far as the pharynx
C	— class C in all other cases.	● Simethicone preparations for oral administration ● Active coal for oral administration ● Gel for vaginal moisturizing / vaginal lubricants ● Eye drops for hydration ● Ear drops for Lubrication ● Medical devices, for oral administration, for the treatment of diarrhoea, e.g. kaolin, dioctahedrite ● Medical devices, for oral administration, for the treatment of obesity, e.g.fructooligosaccharides, glucomannan

Rule 22 Active therapeutic devices with an incorporated diagnostic function

Class	Rule 22	Examples
D	Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class D.	● Automated external defibrillators (AED) including their pads/electrodes ● Semi-automatic external defibrillators ● Automated closed loop insulin delivery system ● Automated external infusion pumps with integrated sensors to adapt the infusion therapy ● Devices in brain–computer interfaces (BCIs) – used for e.g. motor control in severely paralyzed patients ● Closed-loop systems for deep brain stimulation (DBS) treatment of various neurological conditions ● Closed-loop dynamic neurochemical control of therapeutic interventions e.g. target–controlled anaesthesia / infusion systems

The Document Requirement for the New Registration of Medical Devices

Class A (substance–based), Class B, Class C & Class D

Types of Requirements:

A. Administrative documents

B. Medical Device Information

C. Device Labeling

D. Declaration of conformity

E. STED Documentation

F. Other Requirements

A. Administrative documents:

1. Medical Device registration application form should be filled, signed, and stamped by the authorized representative. [The product model number and risk class must be clearly stated in the form]

2. Store License issued from Ministry of Health (Pharmaceutical Inspection & Licensing Administration)

		made of non–degradable polymer, with nanomaterial embedded in the polymer matrix ● Dental filling materials

Rule 20 – Invasive devices, intended to administer medicinal product by inhalation

Class	Rule 20	Examples
B	All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class B	● Spacer intended for metered dose inhalers (attached to the inhaler) unless treating life–threatening conditions. ● Inhalers for nicotine replacement therapy (nicotine not included) ● Oxygen delivery system with a nasal cannula unless treating life–threatening conditions ● Inhalers and nebulisers in case their mode of action has probably no essential impact on the efficacy and safety of the administered medicinal product or which are not intended to treat life–threatening conditions
C	unless their mode of action has an essential impact) on the efficacy and safety of the administered medicinal product or they are intended to treat life–threatening conditions, in which case they are classified as class C	● Nebulisers (not pre–charged with a specific medicinal product) where the failure to deliver the appropriate dosage characteristics could be hazardous ● Spacer intended for metered dose inhalers attached to the inhaler.

Rule 20 – Invasive devices, intended to administer medicinal product by inhalation

Class	Rule 21	Examples
D	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as: class D if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;	
D	class C if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;	● Na/Mg alginate, xyloglucan ● Fat absorbers that are systemically absorbed, themselves or their metabolites
B	class B if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the	● Substance–based formulations for skin treatment ● Salt water used e.g. as nose or throat sprays

Note: For the range of product DOC for all the products should be submitted

E. STED Documentation:[summary of technical documentation should be submitted as per IMDRF guidelines]

STED Contain the following documents:

1. Device Description and Specification, including variants and accessories

In Detail Device Description and Detail Specification/quantitative composition

2. EP checklist:[essential principal check list should be submitted as per IMDRF guidelines]

This section demonstrates how the manufacturer has met the Essential Principles of Safety and Performance. The Essential Principles Application Format may be used to demonstrate compliance in accordance with IMDRF guidelines.

3. Risk management and Benefit–risk assessment

4. Design and manufacture information.

5. Product verification and validation documents (one or more of the following certificates)

● EC/EU Product Quality Management System / Product Quality Assurance Certificate issued from EU–authorized Notified Body (CE mark Certificate)

● EU Technical Document Assessment Certificate/ EU Product verification Certificate issued from EU authorized Notified Body [for higher classes or as applicable]

● United States: Food and Drug Administration (FDA)

● Australia: Therapeutic Goods Administration (TGA)

● Brazil: Agência Nacional de Vigilância Sanitária(ANVISA)

● Canada: Health Canada (HC)

● Japan: Ministry of Health, Labour and Welfare (MHLW)& Pharmaceuticals and Medical Devices Agency (PMDA)

● UK MHRA approval

● Other accredited verification and validation documents

6. TSE/BSE free certificate (if animal origin)

7. Certificate, issued by the manufacturer, stating that the product is free from any pork ingredient or harmful substances. (if applicable)

8. Confirmation that the product does not contain any of the following material (or as per EU acceptable limits)

● Carcinogenic, mutagenic or toxic to reproduction (CMR).

● Substances having endocrine–disrupting properties.

● Phthalates.

9. Certificate of Analysis, including microbiological parameters/sterility (if applicable)

10. Bio–compatibility studies (if applicable)

11. Electrical safety, and electromagnetic compatibility (if applicable)

12. Medicinal substance contained in the medical device, including compatibility between the substance and the device.

3. Agent License issued from Ministry of Health (Pharmaceutical Inspection & Licensing Administration)

4. Original Letter of Appointment;authorisation to appoint the local agent legalized by Kuwait Embassy& the Chamber of commerce in the country of origin.

5. Original Good Manufacturing Practice(GMP) certificate issued from a regulatory authority in country of origin or ISO (13485 Medical Device QMS)/ (13485 MDSAP)relevant International Organization for Standardization certificate for the physical manufacturer , legalized by Kuwait Embassy in the country of origin

6. Original Free Sale Certificate issued from the regulatory authority in the country of origin and legalized by Kuwait Embassy, stating that the products are freely sold in the country of origin.

7. Official Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors & Representative (if applicable)

B. Medical Device information

1. Trade/Brand name.

2. Model name/ number.

3. Medical device classification.

4. Intended use.

5. Pack size(s)

6. Description of accessories.

7. Medical device category.

8. Manufacturer device identification number or UDI

9. Shelf life (if applicable)

10. Storage condition(if applicable)

11. Description of accessories.

12. GMDN Nomenclature

13. Legal Manufacturer name

14. Physical manufacturer name (if applicable)

15. Warnings

Note: for application for the range of device Medical Devices and IVD devices all the above details should be submitted for all the products in the Excel sheet.

C. Device Labeling [as per IMDRF guidelines]

● Colored Labels& IFU (outer pack artwork) for the devices.

Note:

● If the products are in range submit all the range of labels & IFU.

● Electronic IFU for professional use medical devices is accepted

● A representative label may be accepted, provided it is prepared in accordance with applicable regulatory requirements and labeling norms.

D. Declaration of conformity

1. Declaration letter from the legal manufacturer or

2. Declaration of Conformity (DOC) issued from the Legal manufacturer

(DOC should specify the product model number and risk classification)

Quality Assurance Certificate issued from EU–authorized Notified Body (CE Mark Certficate)

• EU Technical Document Assessment Certificate/ EU Product verification Certificate issued from EU authorized Notified Body [for higher classes or as applicable]

• United States: Food and Drug Administration (FDA)

• Australia: Therapeutic Goods Administration (TGA)

• Brazil: Agência Nacional de VigilânciaSanitária(ANVISA)

• Canada: Health Canada (HC)

• Japan: Ministry of Health, Labour and Welfare (MHLW)& Pharmaceuticals and Medical Devices Agency (PMDA)

• UK MHRA approval

• Other accredited verification and validation documents

9. Confirmation that there is no change in the product's composition, specification, shelf life& other parameters since registration

10. An authorization letter issued by the Legal manufacturer/MAH confirming the continuation of the agency with the local agent.

11. Copy of the Registration &variation approvals has issues from Medicine and Medical Products Registration and Regulatory Administration Official

12. Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors & Representative (if applicable)

13. Any additional documents might be required or samples for analysis during or after registration of the product

Note : Renewal application and required documents should be submitted 6 months prior to registration expiration.

The Documents Requirements for the New Registration & the Renewal of Class A Medical Device

1. Letter of Appointment/authorization to appoint the local agent.

2. Good Manufacturing Practice (GMP)certificate issued from regulatory authority in country of origin or ISO (13485 Medical Device QMS)/ (13485 MDSAP) relevant International Organization for Standardization certificate for the physical manufacturer

3. Free Sale Certificate issued from the regulatory authority in the country of origin , stating that the products are freely sold in the country of origin.

4. Official Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors &authorized representative (if applicable)

5. Declaration letter from the legal manufacturer or Declaration of Conformity (DOC) with risk class, DOC should specify the product model number and risk classification

6. Certificate of Analysis including microbiological parameters /sterility (if applicable)

13. Clinical evidence reports (if applicable)

14. General safety and performance/efficacy studies

15. Stability Studies (if applicable)

F. Other Requirements

1. List of countries where the device is registered &marketed

2. Post Market Surveillance (PMS)Control

a. Provide PMS recalls or notices for the last five years(if applicable)

b. PMS Plan Provide a declaration that states the following: We' the name of the company' declare that if one of the products included for registration never featured any recall, post market notice or adverse event, we will inform Pharmaceutical & Herbal Medicines Registration& Control Administration for any PMS Recall and Alert.

3. Samples for registration and analysis as per Kuwait Drug & Food Control Medical Laboratories requirements (if required)

4. Additional Documentation and Samples

The Medicine and Medical Products Registration and Regulatory Administration reserves the right to request any additional documents, information, data, or product samples for evaluation or laboratory analysis, either during the registration process or after the product has been registered, as deemed necessary. Such requests may include information not specifically listed or described in this guideline

The Documents Requirements for the Renewal of Medical Device Class A (substance based medical device) Class B, Class C & Class D

1. Medical Device renewal application form should be filled, signed, and stamped by the authorized representative.

2. Store License issued from Ministry of Health (Pharmaceutical Inspection & Licensing Administration)

3. Agent License issued from Ministry of Health (Pharmaceutical Inspection & Licensing Administration)

4. Original Good Manufacturing Practice (GMP) certificate issued from a regulatory authority in country of origin or ISO (13485 Medical Device QMS)/ (13485 MDSAP)relevant International Organization for Standardization certificate for the physical manufacturer , legalized by Kuwait Embassy in the country of origin

5. Original Free Sale Certificate issued from the regulatory authority in the country of origin and legalized by Kuwait Embassy, stating that the products are freely sold in the country of origin.

6. Medical Device information (Check section 12.B (Medical Device information) in document requirement)

7. Declaration of conformity (Check section 12.D (Declaration of conformity) in document requirement)

8. Product verification and validation documents(one or more of the following certificates)

• EC/EU Product Quality Management system / Product

7. Medical Device information [searchable soft copy should be submitted] (check section 12. B (Medical Device information) for the details)

8. Device Labeling: Colored Labels (artwork)& IFU for the devices

9. Post Market Surveillance (PMS) commitment letter

10. CE mark certificate (If applicable)

Note : Class A substance–based medical devices (medical devices composed of substances), present in pharmaceutical dosage forms, are not covered under this requirement section 14. Such devices are subject to the standard requirements for the registration specified in Section 12 for New Registration & section 13 for renewal of these guidelines.

Rules & Documents requirement for IVD Devices

IVDR Classification Rules

RULE 1

Class	Indent	Examples
D	Rule 1 first indent Devices intended to be used for the detection of, the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration.	• Hepatitis B (HBsAg). • Hepatitis C (Anti–HCV). • Human Immunodeficiency Virus 1/2 (Anti–HIV 1/2).
D	Rule 1 second indent Devices intended to be used for the detection of the presence of, or exposure to, a transmissible agent that causes a life–threatening disease with a high or suspected high risk of propagation	• Hepatitis B Virus • Hepatitis C Virus • Hepatitis D Virus • Haemorrhagic fever viruses • (e.g. Ebola, Marburg, Lassa, Crimean–Congo Haemorrhagic fever • Human Immunodeficiency Virus 1 and 2. • Highly virulent influenza virus. • Human T–Lymphotropic Virus I and II. • SARS COV • MERS Cronavirus • Small poxvirus • Variant Creutzfeldt–Jakob disease
D	Rule 1 third indent Devices intended to be used for determining the infectious load of a life–threatening disease where monitoring is critical in the process of patient management	Devices intended to be used for determining the infectious load of: • Hepatitis B Virus (DNA). • – Hepatitis C Virus. • – Human Immunodeficiency Virus.

RULE : 2

Class	Indent	Examples
D	intended to determine any of the following markers classified as class D	• – ABO system [A (ABO1), B (ABO2), AB (ABO3)] • – Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4

		(c), RH5 (e)] • – Kell system [KEL1 (K)] • – Kidd system [JK1 (Jka), JK2 (Jkb)] • – Duffy system [FY1 (Fya), FY2 (Fyb)]
C	Devices intended to be used for blood grouping , or to determine foeto–maternal blood group incompatibility1, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as class C	• Device intended for HLA typing by Sanger sequencing consisting of reagents for HLA–A, –B, –C, –DRB1, –DQB1 and DPB1 for transplantation purposes. • Medical device software for high–resolution analysis of HLA sequencing data, for transplantation purposes. • Anti–k from clone ID. • Human IgG Antibody. • Blood grouping reagent for transfusion purposes. • Anti–Lea Monoclonal blood grouping reagent for transfusion purposes.

RULE: 3

Class	Indent	Examples
C	Devices intended for detecting the presence of, or exposure to, a sexually transmitted agent	• Chlamydia trachomatis. • Haemophilusducreyi. • Herpes simplex virus 1&2. • Human papilloma virus (HPV). • Neisseria gonorrhoeae. • Mycoplasma hominis. • Mycoplasma genitalium. • Trichomonas vaginalis. • Treponema pallidum. • Ureaplasmaurealyticum. • Monkeypox virus.
C	Devices intended for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation	Devices intended for detecting the presence of: • Bacterial pathogens: Streptococcus pneumoniae, Group B Streptococcus, Neisseria meningitidis, Haemophilus influenza type B, Listeria spp., Borrelia burgdorferi, Mycobacterium tuberculosis. • Fungal pathogens: Cryptococcus neoformans, Aspergillus spp. • Viral pathogens: Herpes simplex virus 1&2, human herpes virus 6, varicella zoster virus, enterovirus, West Nile virus, chikungunya, Dengue, Zika, hepatitis A, hepatitis E. • Parasitic pathogen: Toxoplasma gondii. • Prion agents: sporadic Creutzfeldt–Jakob disease, Gerstmann–Straussler–Scheinker Syndrome, Kuru, Fatal Familial Insomnia.
C	Devices intended for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result	Devices intended for detecting the presence of: • Bacterial pathogens: Treponema pallidum, Chlamydia trachomatis,

			rubella virus in the diagnosis of rubella virus-induced encephalitis. • Assays intended for the detection of antibodies in the recipient to potentially pathogenic viruses (e.g. anti-cytomegalovirus, anti-herpes simplex virus antibodies) to determine latent disease status of viral infection prior to organ or bone marrow transplantation. • – Screening assays comprising allergy panels, such as Multiple Allergen Simultaneous Tests (MAST), intended to detect IgE antibodies against several specific allergens that may lead to anaphylaxis, e.g. certain nutritional allergens or hymenoptera venom allergens. False-negative results with such MAST assays could increase the risk that the patient is not adequately managed for the occurrence of a life-threatening anaphylactic event. • Assays intended for the detection of alloantibodies in the recipient associated with transplant rejection reactions, such as antibodies against – angiotensin II receptors type 1 (anti-AT1R) and against endothelin receptors type A (anti-ETAR). • – Interferon-Gamma Release Assays (IGRA) for Mycobacterium tuberculosis.			
C	Devices intended to be used as companion (CDx) diagnostics	General CDx examples • A device intended to identify a genotype, single or multiple genetic and/or genomic variants • A device intended to identify a marker (receptor, transporter, other protein-based biomarker or its variant) specifically targeted by the corresponding medicinal product. Specific CDx examples • A device intended for the qualitative detection of anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue, intended as an aid in identifying patients eligible for treatment with crizotinib or ceritinib. • A device intended for the quantitative detection of BCR-ABL1 transcripts and the ABL1 endogenous control mRNA in peripheral blood specimens from patients previously diagnosed with t(9;22) positive			

			chronic myeloid leukemia, during treatment with nilotinib. • A qualitative immunohistochemical device using monoclonal mouse Anti-PD-L1, intended for use in the detection of PD-L1 protein in FFPE NSCLC and gastric or gastroesophageal junction (GEJ) adenocarcinoma tissues, that is indicated as an aid in identifying patients for treatment with pembrolizumab. • A polymerase chain reaction based device for the qualitative detection of isocitrate dehydrogenase-2 (IDH2) gene point mutations in DNA extracted from human blood or bone marrow, that is indicated as an aid in identifying acute myeloid leukemia patients with mutated IDH2 enzymes for treatment with enasidenib. • A device intended for the demonstration of individuals homozygous for the non-functional DPYD variant DPYD*2A, that typically have complete dihydropyrimidine dehydrogenase (DPD) deficiency. The DPYD gene encodes DPD, an enzyme that catalyzes the rate-limiting step in fluorouracil metabolism. Capecitabine, a chemotherapy agent used in the treatment of colon cancer, metastatic colorectal cancer, and metastatic breast cancer, is a prodrug that is enzymatically converted to its active form, fluorouracil. Individuals who are carriers of non-functional DPYD variants, may not be able to metabolise capecitabine at normal rates, and are at risk of potentially life-threatening capecitabine toxicity, such as bone marrow suppression and neurotoxicity. • A device intended to identify defined EGFR mutations in order to administer the tyrosine-kinase inhibitor dacomitinib for the treatment of adult patients with locally advanced or metastatic (NSCLC) and EGFR-activating mutations. • A next-generation sequencing (NGS) based device to evaluate KRAS/NRAS genetic variants to determine the presence of mutations affecting the efficacy of vectibix for treatment of metastatic colorectal cancer.			
C	Devices intended to be used in screening, diagnosis, or staging of cancer	• A faecal occult blood screening test (FOBT) or faecal immunochemical test (FIT) specifically intended to be used in colon cancer screening. • A device intended for the quantitative/qualitative determination of IgG antibodies to Helicobacter pylori in human blood samples specifically intended to be used in gastric cancer screening. • Papanicolaou (Pap) stain automated cervical cytology screening system, intended to process Pap cervical cytology slides and classify the cervical specimen as either normal or abnormal. • A qualitative real-time PCR test intended for the detection of high-risk genotypes of Human Papillomaviruses for use in cervical cancer screening. • Immunohistochemistry assay intended for the detection of c-KIT or CD117 tyrosine kinase receptor expression in normal and neoplastic formalin-fixed, paraffin-embedded tissues for histological evaluation, and gene mutation testing for KIT and platelet-derived growth factor receptor alpha in (familial) gastro-intestinal stromal tumor. • Assay for the quantitative determination of the cancer associated antigen CA 125			
C	Devices intended to be used in screening, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring	• Device intended for the quantitative measurement of Brain type natriuretic peptide (BNP) in whole blood or plasma samples, for the assessment of the severity of congestive heart failure. • Devices intended for staging of enhanced liver fibrosis (ELF) for detecting the following markers: hyaluronic acid; procollagen III amino terminal peptide, tissue inhibitor or metalloproteinase. • Medical device software intended to generate an estimated glomerular filtration rate (eGFR) or albumin creatinine ratio (ACR) for staging acute kidney injury (AKI). • Medical device software intended to generate an enhanced liver fibrosis (ELF) score which correlates to the level of fibrosis. • Medical device software intended to generate a model for end stage liver disease (MELD) score.			

		to ensure that the sample detection and identification systems are performing when using the CTC Kit. They express epithelial cell markers recognised by the antibodies in the Circulating Tumour Cell Kit and are used as a control for the performance of the assay. • An image analysis medical device software intended to aid in the detection and semi-quantitative measurement of programmed death ligand 1 (PD- L1) protein in FFPE lung tissue. The algorithm is an adjunctive computer-assisted methodology for a qualified pathologist in the acquisition
C	Devices intended for human genetic testing	• Newborn Screening: Newborn screening is used just after birth to identify genetic disorders to detect potentially fatal or disabling conditions. Such early detection allows treatment to begin immediately, which can reduce or eliminate the effects of the condition. • Diagnostic testing: Diagnostic testing is used to identify or rule out a specific genetic or chromosomal condition. • Carrier testing: Carrier testing is used to identify people who carry one copy of a gene mutation that could result in a genetic disorder in one's offspring. For some genetic disorders, two copies of the gene mutation are required to cause the genetic disorder (autosomal recessive). Whereas for others, one copy of the gene mutation is required either i) in the absence of a second normal copy resulting in the genetic disorder (X-Linked recessive) or ii) in the presence of a normal copy can result in a genetic disorder (autosomal dominant). This type of testing provides information about a couple's risk of having a child with a genetic condition. • Prenatal testing: Prenatal testing is used to detect changes in a foetus's genes or chromosomes before birth. • Preimplantation testing: Preimplantation testing, also called preimplantation genetic diagnosis (PGD), is a specialized technique used to detect genetic changes in embryos obtained through in vitro fertilization. • Predictive and presymptomatic testing:

		(colonic epithelium-related glycoprotein associated with epithelial ovarian cancer) in serum. • Immunohistochemistry assay intended to detect progesterone receptor in breast tumours to be used as an aid in the management, prognosis, and prediction of therapy outcome of breast carcinoma. • Fluorescence in situ hybridisation (FISH) panels intended for the diagnosis of e.g. lymphoma, multiple myeloma and leukaemia. • Targeted next generation sequencing test intended to be used in (haemato)-oncology, to detect acquired somatic mutations in DNA isolated from formalin-fixed paraffin embedded (FFPE) tumour tissue specimens. • BRCA1 device intended for the detection of deletions or duplications in the human BRCA1 gene in order to confirm a potential cause and clinical diagnosis for hereditary breast and ovarian cancer and for molecular genetic testing of at-risk family members. • Device applied in testing services intended for the analysis of 35 genes relevant to digestive tract tumours (various forms of colorectal cancer, stomach cancer and pancreatic cancer), breast cancer, ovarian cancer, skin cancer, thyroid tumours, and endocrine tumours (panel), intended to provide information on whether an individual carries genetic alterations that favour the onset of specific tumour diseases, identifying these genetic predispositions. • Circulating Tumour Cell Kit (Epithelial) intended for the enumeration of circulating tumour cells (CTC) of epithelial origin in whole blood. The test is to be used as an aid in the monitoring of patients with metastatic breast, colorectal or prostate cancer. Serial testing for CTC should be used in conjunction with other clinical methods for monitoring metastatic breast, colorectal and prostate cancer, to allow assessment of patient prognosis and is predictive of progression free survival and overall survival. • Breast carcinoma cell line (SK-BR-3) CTC Cell Control Kit intended as an assay control

		Predictive and presymptomatic types of testing are used to detect gene mutations associated with disorders that appear after birth, often later in life. Predictive testing can identify mutations that increase a person's risk of developing disorders with a genetic basis. Presymptomatic testing can determine whether a person will develop a late-onset genetic disorder. • – Direct-to-Consumer (DTC) genetic testing: genetic testing provided through advertising and selling or (free) provision of genetic tests directly to consumers.
C	Devices intended for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring	• Devices intended for monitoring: • Cardiac marker for acute presenting patients Troponin I, Troponin T, CKMB (when intended for monitoring cardiac muscle injury). • Cortisol levels monitoring e.g. for patients with cortisol insufficiency. • PT/APTT testing in patients with major bleeds in acute presentations or patients with acute coagulopathy or for coumadin monitoring in patients without diagnosed coagulation disorder. • Lithium for patients being treated for bipolar disorders. • Methotrexate when used for treating non-life threatening conditions such as vasculitis, rheumatoid arthritis and psoriatic arthritis). • Immunosuppressive (anti-rejection) medicinal products e.g. cyclosporine, sirolimus, tacrolimus. • Antibiotic where under/over treatment can have a serious impact on individual or offspring e.g gentamicin. • Anti-RhD antibody levels in pregnant women given additional Anti-D. • Blood amylase e.g. acute pancreatitis, perforated peptic ulcer, acute biliary obstruction. • Acute phase reactants e.g. C-reactive protein (CRP), procalcitonin when intended to be used to monitor infection response to therapy for life threatening conditions such as sepsis, necrotizing skin or tissue conditions, infective endocarditis, bacterial meningitis etc. • Full blood count when used for monitoring for the

		development of a life threateninghaematological disorder in patients being treated for other disorders/conditions, where this risk exists e.g. monitoring of patients with a diagnosis of schizophrenia for neutropenia/agranulocytosis. • Bilirubin in response to treatment of neonatal jaundice.
C	Devices intended for management of patients suffering from a life-threatening disease or condition	• Devices intended for: Enumeration of CD4 T lymphocytes in HIV infected patients to initiate treatment and ascertain the anti-viral therapy response. • Measurement of D-Dimers in patients with thrombotic disorders. • Laboratory risk score calculator indicator for necrotising fasciitis in necrotising soft tissue infections. • HbA1c and blood glucose tests for the management of patients with diabetes. • Monitoring anticoagulant therapy e.g. prothrombin Time/INR (warfarin), APTT (unfractionated heparin), anti-Xa chromogenic assays (low molecular weight heparin (LMWH), fondaparinux, rivaroxaban, and apixaban), anti-IIa chromogenic and clot-based assays (argatroban, bivalirudin, hirudin, and dabigatran). • Digoxin monitoring. • Anti-retroviral resistance testing in HIV infected patients.
C	Devices intended for screening for congenital disorders in the embryo or foetus	• Devices intended for screening of foetal aneuploidies (e.g. trisomy 13, trisomy 18 and trisomy 21), which include devices intended for the measurement of biochemical maternal serum markers. • Reagents and medical device software evaluating the risk of foetal aneuploidies based on biochemical markers and other information, in particular non-invasive prenatal tests (NIPT). • Devices intended to determine the foetal sex in cell-free foetal DNA in maternal blood, in the remit of sex-depending congenital disorders. • Genetic test for cystic fibrosis. • Genetic test for sickle cell disease. • Huntington's chorea. • Tay Sachs. • Thalassaemia and other haemoglobin disorders.
C	Devices intended for screening for congenital	Examples of devices intended for screening in new-born

		and sends an image of the result to be interpreted by a healthcare professional are in class C. • Self-testing devices for detection of HIV antibodies from a fingerprick blood sample are in class D (as per Rule 1). • Self-testing devices intended for the detection of SARS CoV-2 or antibodies against SARS CoV-2 are in class C.
B	devices for the detection of pregnancy; for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B	• devices for the detection of pregnancy, for fertility testing, and for determining cholesterol level in any specimen, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine,

Devices intended for near-patient testing are classified in their own right

Class	Indent	Examples
	Devices intended for near-patient testing are	• Class D (under Rule 1): Rapid test for detection of human immunodeficiency virus. • Class D (under Rule 2): Pre-transfusion ABO compatibility test cards intended to be used at the recipients' bedside as precaution against ABO-incompatible transfusion. • Class C (under Rule 3): Blood glucose reagents ; strips for patient monitoring. • Class C (under Rule 3): Mobile cardiac marker monitoring test for acute presenting patients: Troponin I, Troponin T, CKMB (when intended to be used for monitoring cardiac muscle injury). • Class C (under Rule 3): Rapid test for the detection of methicillin-resistant Staphylococcus aureus. • Class B (under Rule 6): Urine dipstick to determine urinary tract infection at point of care. • Class B (under Rule 6): Quantitative test for haemoglobin as an aid in diagnosing iron deficiency. • Class B (See Rule 6): Rapid tests for the detection of Group A Strep, Respiratory Syncytial Virus, and Influenza virus(es).

RULE : 5

Class	Indent	Examples
A	a) Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific	• General microbiological culture media containing selecting agents, antimicrobial chromogenic agents, chemical indicators for colour differentiation. • Solutions like cleaners, buffer solutions, lysing solutions, diluents specified for use with an IVD. • Pipette with a specific fixed one volume specifically intended for a particular IVD

	disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities	babies for congenital disorders: • Beta-thalassaemia. • Biotinidase deficiency. • Congenital adrenal hyperplasia – e.g. 17-hydroxyprogesterone (17-OHP). • Congenital hypothyroidism – e.g thyroxine. • Cystic fibrosis – e.g. mutation and variant screening, immunoreactive trypsin. • Galactosaemia – e.g. total galactose or galactose-1-phosphate uridyltransferase. • Glutaric aciduria type 1. • Hyperphenylalaninaemia / phenylketonuria e.g phenylalanine (in blood); phenylpyruvic, phenyllactic, 2-OH phenylacetic (in urine). • Homocystinuria (pyridoxine unresponsive) e.g. free homocystine, total homocysteine, and methionine (in blood and urine). • Isovaleric acidaemia. • Maple syrup disease (MSUD IA, IB, II) – e.g. branched-chain amino acids, allo isoleucine (in blood); branched-chain 2-ketoacids, branched-chain 2-hydroxy acids (in urine). • Medium-chain acyl-CoA dehydrogenase deficiency – e.g. acylcarnitine measurement. • Methylmalonic aciduria including cblA, cblB, cblC and cblD. • Propionic aciduria. • N-Acetylglutamate synthase deficiency – e.g. glutamine, alanine, citrulline, arginine (in blood). • Sickle-cell disease. • Tyrosinemia (I, II, III) – e.g. tyrosine (in blood); succinylacetone, 4-OH phenylpyruvic, 4-OH phenyllactic acids (in urine). • Severe combined immunodeficiency (SCID) e.g. by TREC/KREC determination.

Rule : 4

Class	Indent	Examples
C	Devices intended for self-testing are classified as class C,	• Meters and strips (containing integrated testing reagent) for self-testing of capillary blood glucose are in class C. • Self-testing devices for blood clotting, e.g. measurement of International Normalised Ratio (INR) are in class C. • Devices intended to measure the levels of calprotectin where the lay person collects the stool specimen, carries out the testing procedure using the test cassette

		establishing the identification of microbiological culture isolates or for determining antimicrobial susceptibility of microbiological culture isolates except those permitting identification or determination of MIC associated with a life threateningcondition. • Test to detect Helicobacter pylori, Clostridium difficile, adenovirus, rotavirus and Giardia lamblia. • Non-typhoidal anti-salmonella antibodies to detect the exposure to an infectious agent. • FSH device for fertility testing in blood. • Device intended for the detection of Candida albicans. • Device intended for the detection of or exposure to Entamoeba histolytica. • Device intended for the detection of Sarcoptesscabiei(genital scabies). • Assay intended for the detection of autoantibodies (e.g. anti-smRNP and anti-SSA/Ro) associated with systemic lupus erythematosus (SLE), anti-neutrophil cytoplasmic antibodies [ANCAs] in systemic vasculitis), anti-aquaporin-4 antibodies (anti-AQP4) in neuromyelitis optica spectrum disorders (NMOSDs) or organ-specific autoimmune diseases (e.g anti-Insulin antibodies in insulin-dependent diabetes). • Antibody tests for HAV, dengue, chikungunya and West Nile virus. • Assay intended for the detection of IgG antibodies against HEV. • Device intended for the detection of Influenza A/B virus (not highly virulent). • Device intended for the detection of SARS-CoV-2. • Device intended for the detection of antibodies against SARS-CoV-2.

Rule 7

Class	Indent	Examples
B	Devices which are controls without a quantitative or qualitative assigned value are classified as class B	• Unassigned control sera. • Control materials used to verify the migration of immunochromatographic assays. • Unassigned QC Material as a heterozygous quality control to monitor analytical performance of the extraction, amplification and detection.

	examination	test with specified human sample, e.g. blood coagulation pipettes with automatic timing (Accessory of coagulometer). • General staining reagents like hematoxylin, eosin, pap and grams iodine. • Kits for Isolation and purification of nucleic acids from human specimens. • Library Prep reagents for preparation of DNA for downstream analysis by NGS sequencing. Nucleic acid quantitation kits. • General reagents (not assay specific) used with a Class A instrument, e.g. general sequencing consumable reagents used with a sequencer.
A	Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures	• Enzyme immunoassay analyser, PCR thermocycler, sequencer for NGS applications, clinical chemistry analyser. • Instrument for automated purification of nucleic acids and PCR set-up.
A	Specimen receptacles	• A standalone urine collection cup, a stool container, a saliva collection tube or a blood spot collection card (e.g. specimen collection via finger-prick) intended for subsequent in vitro diagnostic examination are in class A. • Standalone kits intended for the collection of saliva by the lay person for the purpose of detection of SARS-CoV-2 (by another device placed on the market separately) are in class A. • Standalone kits intended for the collection of stool by the lay person for the purpose of faecal occult blood detection in colorectal cancer screening by a professional laboratory (with another device placed on the market separately), including a paper sheet to collect stool, a plastic stick to collect samples and a pre-filled tube for conservation and transport are in class A.

RULE 6

Class	Indent	Examples
B	Devices not covered by the above-mentioned classification rules are classified as class B	• Device intended to detect and measure magnesium to assess electrolyte / magnesium homeostasis. • Test intended to detect and measure C-reactive protein or calprotectin to detect systemic inflammatory processes due to an active disease. • Biochemical test for

13. Legal Manufacturer name
14. Physical manufacturer name (if applicable)
15. Warnings
Note: for application for the range of device Medical Devices and IVD devices all the above details should be submitted for all the products in the Excel sheet.
C. Device Labeling [as per IMDRF guidelines]
• Colored Labels& IFU (outer pack artwork) for the devices.
Note:
• if the products are in range submit all the range of labels & IFU.
• Electronic IFU for professional use IVD devices is accepted
• A representative label may be accepted, provided it is prepared in accordance with applicable regulatory requirements and labeling norms.
D. Declaration of conformity
1. Declaration letter from the legal manufacturer or
2. Declaration of Conformity (DOC) issued from the Legal manufacturer
(DOC should specify the product model number and risk classification)
Note: For the range of product DOC for all the products should be submitted
E. STED Documentation [summary of technical documentation should be submitted as per IMDRF guidelines]
STED Contain the following documents:
1. Device Description and Specification, including variants and accessories, in Detail Device Description and Detail Specification/quantitative composition
2. EP checklist [essential principal check list should be submitted as per IMDRF guidelines] This section demonstrates how the manufacturer has met the Essential Principles of Safety and Performance. The Essential Principles Application Format may be used to demonstrate compliance in accordance with IMDRF guidelines.
3. Risk management and Benefit–risk assessment
4. Design and manufacture information.
5. Product verification and validation documents (one or more of the following certificates)
• EC/EU Product Quality Management System / Product Quality Assurance Certificate issued from EU–authorised Notified Body (CE Mark Certificate)
• EU Technical Document Assessment Certificate/ EU Product verification Certificate issued from EU authorized Notified Body
[for higher classes or as applicable]
• United States: Food and Drug Administration (FDA)
• Australia: Therapeutic Goods Administration (TGA)
• Brazil: Agência Nacional de Vigilância Sanitária(ANVISA)
• Canada: Health Canada (HC)

		• Non–assay specific control plasmas for use in coagulation. • Non–assay specific control serum containing multiple biochemical analytes. • A DNA or RNA probe supplied for use as a non–assay specific normal control for in situ hybridisation (ISH).

The Document Requirement for the New Registration of Class B, Class C & Class D IVD Devices
Types of Requirements:
A. Administrative documents
B. IVD Device Information
C. Device Labeling
D. Declaration of conformity
E. STED Documentation
F. Other Requirements
A. Administrative documents:
1. IVD Device registration application form should be filled, signed, and stamped by the authorized representative. [The product model number and risk class must be clearly stated in the form]
2. Store License issued from Ministry of Health (Pharmaceutical Inspection & Licensing Administration)
3. Agent License issued from Ministry of Health (Pharmaceutical Inspection & Licensing Administration)
4. Original Letter of Appointment/authorisation to appoint the local agent legalized by Kuwait Embassy& the Chamber of commerce in the country of origin.
5. Original Good Manufacturing Practice(GMP) certificate issued from a regulatory authority in country of origin or ISO (13485 Medical Device QMS)/ (13485 MDSAP)relevant International Organization for Standardization certificate for the physical manufacturer , legalized by Kuwait Embassy in the country of origin
6. Original Free Sale Certificate issued from the regulatory authority in the country of origin and legalized by Kuwait Embassy, stating that the products are freely sold in the country of origin.
7. Official Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors & Representative (if applicable)
B. IVD Device information
1. Trade/Brand name.
2. Model name/ number.
3. IVD device classification.
4. Intended use.
5. Pack size(s)
6. Description of accessories.
7. IVD device category.
8. Manufacturer device identification number or UDI
9. Shelf life (if applicable)
10. Storage condition(if applicable)
11. Description of accessories.
12. GMDN Nomenclature

(Pharmaceutical Inspection & Licensing Administration)
3. Agent License issued from Ministry of Health (Pharmaceutical Inspection & Licensing Administration)
4. Original Good Manufacturing Practice (GMP) certificate issued from a regulatory authority in country of origin or ISO (13485 Medical Device QMS)/ (13485 MDSAP)relevant International Organization for Standardization certificate for the physical manufacturer , legalized by Kuwait Embassy in the country of origin
5. Original Free Sale Certificate issued from the regulatory authority in the country of origin and legalized by Kuwait Embassy, stating that the products are freely sold in the country of origin.
6. Medical Device information (Check section 16.B (IVD Device information) in document requirement)
7. Declaration of conformity (Check section 16.D (Declaration of conformity) in document requirement)
8. Product verification and validation documents(one or more of the following certificates)
• EC/EU Product Quality Management system / Product Quality Assurance Certificate issued from EU–authorized Notified Body (CE Mark Certificate)
• EU Technical Document Assessment Certificate/ EU Product verification Certificate issued from EU authorized Notified Body [for higher classes or as applicable]
• United States: Food and Drug Administration (FDA)
• Australia: Therapeutic Goods Administration (TGA)
• Brazil: Agência Nacional de VigilânciaSanitária(ANVISA)
• Canada: Health Canada (HC)
• Japan: Ministry of Health, Labour and Welfare (MHLW)& Pharmaceuticals and Medical Devices Agency (PMDA)
• UK MHRA approval
• Other accredited verification and validation documents
9. Confirmation that there is no change in the product's composition, specification, shelf life& other parameters since registration
10. An authorisation letter issued by the Legal manufacturer/MAH confirming the continuation of the agency with the local agent.
11. Copy of the Registration &variation approvals has issues from Medicine and Medical Products Registration and Regulatory Administration
12. Official Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors & Representative (if applicable)
13. Any additional documents might be required or samples for analysis during or after registration of the product
The Documents Requirements for the New Registration & the Renewal of Class A IVD Devices
1. Letter of Appointment/authorisation to appoint the local agent.
• Japan: Ministry of Health, Labour and Welfare (MHLW)& Pharmaceuticals and Medical Devices Agency (PMDA)
• UK MHRA approval
• Other accredited verification and validation documents
6. Certificate, issued by the manufacturer, stating that the product is free from any pork ingredient or harmful substances.(if applicable)
7. Confirmation that the product do not contain any of the following material (or as per EU acceptable limits)
• Carcinogenic, mutagenic or toxic to reproduction(CMR).
• Substances having endocrine–disrupting properties.
• Phthalates.
8. Certificate of Analysis, including microbiological parameters/sterility(if applicable)
9. Bio–compatibility studies (if applicable)
10. Electrical safety, and electromagnetic compatibility(if applicable)
11. Clinical evidence/ evaluation reports (if applicable)
12. General safety and performance/efficacy studies (performance evaluation report, analytical
13. performance report) (if applicable)
14. Stability Studies (if applicable)
15. software validation report (if applicable)
F. Other Requirements
1. List of countries where the device is registered &marketed
2. Post Market Surveillance (PMS) Control
a. Provide PMS recalls or notices for the last five years(if applicable)
b. PMS Plan Provide a declaration that states the following:
We' the name of the company' declare that if one of the products included for registration never featured any recall, post market notice or adverse event, we will inform Kuwait Pharmacovigilance Center for any PMS Recall and Alert.
3. Samples for registration and analysis as per Kuwait Drug & Food Control Medical Laboratories requirements (if required)
4. Additional Documentation and Samples
The Medicine and Medical Products Registration and Regulatory Administration reserves the right to request any additional documents, information, data, or product samples for evaluation or laboratory analysis, either during the registration process or after the product has been registered, as deemed necessary. Such requests may include information not specifically listed or described in this guideline
The Document Requirements for the Renewal of Class B, C & D IVD Devices
1. IVD Device renewal application form should be filled, signed, and stamped by the authorized representative.
2. Store License issued from Ministry of Health

Devices specification /product formulation (Active or Non-active), shelf life, specification, storage conditions, label, manufacturing site, manufacturer...etc.. Should be reported to the Medicine and Medical Products Registration and Regulatory Administration . For any type of variation, set of required documents must be provided and any changes cannot be implemented prior to Administration approval.

Variation guideline issued by Medicine and Medical Products Registration and Regulatory Administration , and will be periodically updated.

Suspension of Registration circumstances

1. Medicine and Medical Products Registration and Regulatory Administration the right to suspend the registration of a medical device under any of the following circumstances:

2. Where the medical device or the legal manufacturer has been suspended, withdrawn or restricted by the competent authority in the country of origin.

3. Where evidence is identified indicating non-compliance with applicable safety, quality, or performance (efficacy) requirements.

4. Where the legal manufacturer or involved facility fails to comply with applicable Good Manufacturing Practice (GMP) requirements.

5. Where the medical device does not conform to the specifications, design, or intended use as declared by the legal manufacturer.

6. Where discrepancies, inconsistencies, or falsifications are identified in the submitted documentation.

7. Where there is non-compliance with the laws, regulations, or regulatory requirements of the Pharmaceutical and Herbal Medicines Registration and Control Administration.

8. Where the Medicine and Medical Products Registration and Regulatory Administration becomes aware, through any source other than the local authorized representative, of a safety alert, warning, recall, restriction, or regulatory action issued by the FDA, EMA, WHO, GCC authorities, or any other recognized international health or regulatory body concerning the medical device or the legal manufacturer's site

Registration Cancellation Circumstances

1. Medicine and Medical Products Registration and Regulatory Administration reserves the right to cancel the registration of a medical device under any of the following circumstances:

2. Where the product fails to comply with the

2. Good Manufacturing Practice (GMP)certificate issued from regulatory authority in country of origin or ISO (13485 Medical Device QMS)/ (13485 MDSAP) relevant International Organization for Standardization certificate for the physical manufacturer

3. Free Sale Certificate issued from the regulatory authority in the country of origin , stating that the products are freely sold in the country of origin.

4. Official Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors & Representative (if applicable)

5. Declaration letter from the legal manufacturer or Declaration of Conformity (DOC) with risk class ,DOC should specify the product model number and risk classification

6. Certificate of Analysis including microbiological parameters /sterility (if applicable)

7. Medical Device information [searchable soft copy should be submitted] (check section 16. B (IVD Device information) for the details)

8. Device Labeling: Colored Labels (artwork)& IFU for the devices

9. Post Market Surveillance (PMS) commitment letter

10. CE mark certificate (If applicable)

Laboratory products for non-medical purposes:

A. The labelling of General Laboratory Use (GLU) products shall indicate that the device is For General laboratory Use and Not Specifically for medical use or for use in diagnostic procedures.

Example:

- Centrifuge Scales Balances
- Incubators that are not intended to cultivate microorganisms or for the purpose of diagnosis of disease
- Drying oven
- Autoclave for general laboratory use
- Multipurpose tubes/ multipurpose containers Pipettes
- Mixers Shakers

B. All general reagents, calibrators, indicators, buffers etc, which are used for non-clinical / non-medical purposes are not considered IVD medical devices.

Note : These products shall obtain an import permit from Medicine and Medical Products Registration and Regulatory Administration as non-medical IVD, " If only imported/claimed to be used in the Medical field institutions".

Variation

Any major or minor changes in the Medical device/IVD

the old and new local agents.

2. Drug & Food Control Registration & Control Administration will not be included or legally interrupted in the details or conditions of agreements, authorization or termination letters.

3. The agency transfer will be assessed based on valid legalized documents which should be trustworthy

4. Where the product registration has expired, the newly appointed local agent shall be required to submit a new registration application, in full compliance with all applicable requirements set forth in Sections 12 and 16 of these Guidelines, together with an original, duly legalized termination letter issued to the previous local agent.

References

1. IMDRF: International Medical Device Regulators Forum (IMDRF)

2. Regulation (EU) 2017/745 is a regulation of the European Union

3. Regulation (EU) 2017/746 is a regulation of the European Union

4. Federal Food, Drug & Cosmetic Act-U.S. Food & Drug Administration(FDA)

5. United States: Food and Drug Administration (FDA) Medical Device Regulation

6. Australia: Therapeutic Goods Administration (TGA)

7. Brazil: Agência Nacional de VigilânciaSanitária (ANVISA)

8. Canada: Health Canada (HC) Medical Device Regulation

9. Japan: Ministry of Health, Labour and Welfare (MHLW) & Pharmaceuticals and Medical Devices Agency (PMDA)

10. The Gulf Health Council (GHC) & GCC authorities Guidelines

11. Bahrain Medical Device Registration Guidelines

12. Oman Medical Device Registration Guidelines

13. Food and Drug Authority (SFDA) Medical Device Registration Guidelines

14. Classification of medical devices – European Commission

specifications, composition, design, or intended use as declared by the legal manufacturer.

3. Upon a formal written request or instruction from the legal manufacturer to cancel the product registration.

4. Where the Administration becomes aware, through any source other than the local authorized representative, of any warning, safety alert, recall, suspension, or regulatory action issued by the FDA, EMA, MHRA, WHO, GCC authorities, or any other recognized international regulatory or health authority concerning the medical device or the manufacturing site.

5. Where the local authorized representative fails to renew the product registration within the proscribed renewal period.

6. Where the company fails to submit adequate data or documentation to support the lifting of a suspension within six (6) months from the date of suspension.

7. Where undeclared pharmaceutical or active ingredients are detected during laboratory analysis conducted by the Ministry of Health.

8. Where the product fails to comply with the provisions, requirements, or conditions stipulated under this Ministerial Decree or any applicable laws and regulations issued by the Medicine and Medical Products Registration and Regulatory Administration.

Requirements for Transfer of Agency

1. Medical Device transfer application form should be filled, signed, and stamped by the authorized representative.

2. Store License issued from Pharmaceutical Inspection & Licensing Administration

3. Agent License issued from Pharmaceutical Inspection & Licensing Administration

4. Original letter for appointment for new local agent, from the legal manufacturer legalized by Kuwait Embassy and the Chamber of Commerce in the country of origin company.

5. Original termination letter of the old local agent, from the legal manufacturer company legalized by Kuwait Embassy in the country of origin, must include termination date.

6. List of the registered products issued by the legal manufacturer.

Terms and Conditions of Agency Transfer

1. Medicine and Medical Products Registration and Regulatory Administration will not be responsible for any illegal practices or legal disputes and conflicts that can exist between the MAH & the previous local agent or between