Is the new MDCG 2021-24 'Guidance on Classification of Medical Devices' worth reading? Yes, definitely!

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The new MDCG 2021-24 'Guidance on Classification of Medical Devices' was finally released last week. In case you're wondering if the whole 57-pages document is worth reading from beginning to the end, we would say, "Yes, definitely." While it's not perfect, it helps ease some confusion about how to best apply the rules, when there are two or more that fit, or if your product is a system containing several components, or if it is difficult to find a suitable rule at all.

Let's go directly to the main thing, *section 4. Explanations of Individual Rules*. Its *subsection 4.1 Graphical Summary* may not be easy to follow on its own, but it gives you a heads-up of what's coming later. As you can see in the example below for **Invasive Devices**, you might wonder about the red text. Essentially, when examining Rule 5 here, you shouldn't be easily satisfied that your product belongs to class X according to Rule 5, but you should also examine Rules 4, 20, and 21 to see whether additional rules are applicable to your product as well in order to ensure that you use the correct (i.e., the highest applicable) class. Another important note: you should always check all Rules (yes, from 1 to 22!) to make sure that you don't miss anything. A good RA professional should always do this! Still confused with the graphic summary? Keep reading.

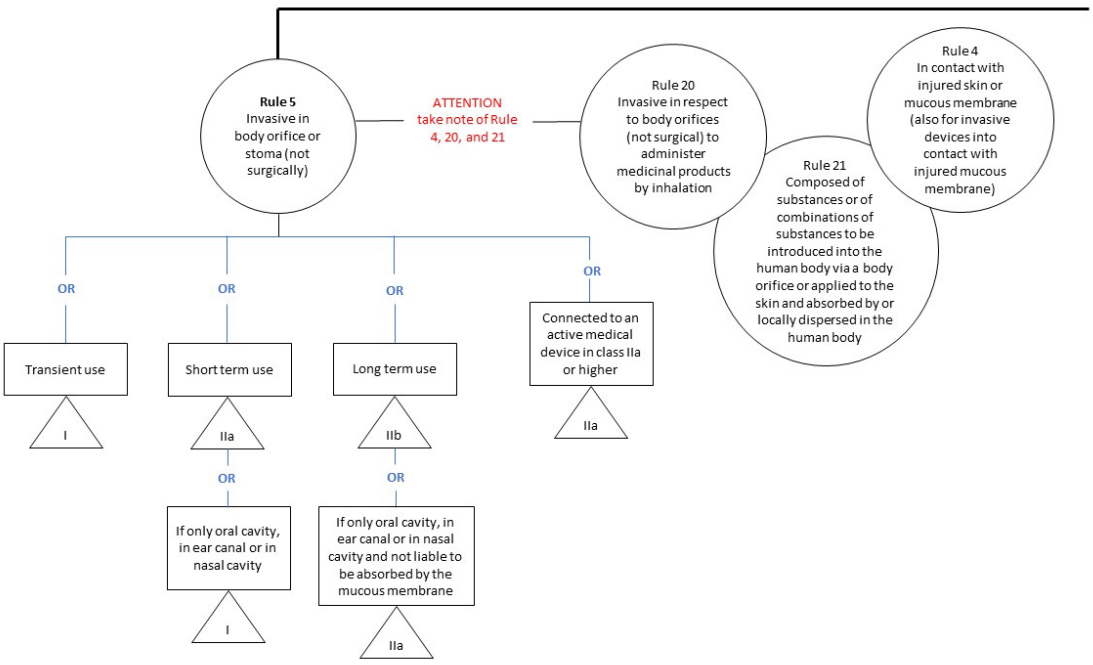

Figure 1: Graphic summary of Rule 5

The next *subsection 4.2 General Explanation of Rules/Practical Issues/Examples* provides you with a better explanation by breaking down each part of the individual rule and providing you with some examples of products (see Table 1 below).

Table 1: Examples of devices classified under Rule 10

Class	Rule 10	Examples
IIa	Active devices intended for diagnosis and monitoring are classified as class IIa: - 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
I	except for devices intended to illuminate1 the patient's body, in the visible spectrum, in which case they are classified as class I;	• Examination lamps • Surgical microscopes intended to illuminate the patient's body in the visible spectrum • Dermatoscopes with integrated light sources
IIa	- if they are intended to image in vivo distribution of radiopharmaceuticals; or	• Gamma cameras • Positron emission tomography and single photon emission computer tomography
IIa	- if they are intended to allow direct diagnosis2 or monitoring of vital physiological processes,	• Electrocardiographs • Electroencephalographs • Electronic thermometers • Electronic stethoscopes • Electronic blood pressure measuring equipment
IIb	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 IIb.	• 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
IIb	Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology device and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.	• Diagnostic X-Ray machine • Computed Tomography Devices

A big WARNING, though! You should not go through all the examples given in the guidance and try to match your product to one of them and see which rule applies. Why? As you can see below, similar (or even the same) generic product names are used in those examples for different rules and assigned to different classes. Unless you take into account your product`s intended use, specific description and specification, materials, etc., you might end up with a wrong class and/or applicable Rule.

Table 2: An example where syringes are classified under Rule 2

Class	Rule 2	Examples
IIa	All non-invasive devices intended for channeling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa: - if they may be connected1 to a class IIa, class IIb or class III 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 intended to be used as channels in active drug delivery systems, e.g., tubing intended for use with an infusion pump • 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)
IIb	- except for blood bags; blood bags are classified as class IIb.	• Blood bags without a substance which, if used separately, can be considered to be a medicinal product
I	In all other cases, such devices are classified as class I	• 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 medicines • Empty syringes without needles

Table 3: An example where syringes are classified under Rule 5

Class	Rule 5	Examples
I	All invasive devices with respect to body orifices, other than surgically 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;	• Handheld mirrors used in dentistry to aid in dental diagnosis and surgery • Dental impression materials • Stomach tubes • Impression trays • Examination gloves • Urinary catheters intended for transient use • Embryo transfer catheter and insemination catheter
IIa	- class IIa if they are intended for short-term use,	• Short term corrective contact lenses • Tracheal tubes • Indwelling urinary catheters intended for short term use • Gasses used for insufflation in the body • Nasobilliary tubes
I	- 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 I; and	• Materials for dental impressions • Plastic syringes used to measure a quantity of medicinal product before oral administration to the patient • Removable or fixed dental prostheses
IIb	- class IIb 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
…	…	…

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Table 4. An example where syringes are classified under Rule 6

Class	Rule 6	Examples
IIa	All surgically invasive devices intended for transient use are classified as class IIa unless they:	• 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
III	- 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 III;	• 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
…	…	…

The *subsection 4.2 General Explanation of Rules/Practical Issues/Examples* is also helpful in ways that it gives you general explanation of the rule and important notes with explanation of special concepts and practical issues that may come across the classification process. For Rule 10 **Active devices for diagnosis and monitoring or intended for diagnostic or therapeutic radiology**, for example, it explains what 'illuminate' and 'ionising radiation' mean. Moreover, it also gives warning notes that devices for recording diagnostic X-ray images are covered by Rule 17 and devices specifically intended to monitor active implantable devices fall under Rule 8 or Rule 9, instead of Rule 10.

Generally speaking, the guidance is helpful but not perfect. In addition to the examples described above, it is helpful in that it provides some additional information on important basic terms and definitions, like continuous use, invasiveness, or active devices. The *subsection 3.1.6 Devices with a Measuring Function* is another example. It explains that devices for delivery of medicine without graduation or scale (e.g., medicine spoons, droppers, cups without graduation or scale) do not belong to this category. Only those with graduation or scale which is displayed in legal unit (e.g., ml, cc) belong to this category. When we say the guidance is not perfect, incorrect definition of short-term use is one example. The definition of short-term use in Annex VIII of the MDR "´short-term´ means normally intended for continuous use for between 60 minutes and 30 days" **includes** the margins, i.e., 60 minutes and 30 days, while ´transient` is less than 60 minutes and ´long-term´ more than 30 days. The MDCG guidance, however, while citing the MDR correctly in section *3.1.2 Duration of Use*, then excludes the duration of exact 60 minutes or exact 30 days in explaining Rule 7 **Surgically invasive devices intended for short-term use (> 60 min < 30 days)** in section *4.2.2 Invasive Devices*.

Alright then, we highlighted the most interesting points from the MDCG 2021-24 that can help you to correctly classify your medical devices. Now, go on download the guidance, have a look, enjoy and good luck with classifying your products. Of course, if you still need some help for this matter, do not hesitate to contact us at QUNIQUE to support you with product classification.

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You can get in touch with us at info@quniquegroup.com or book one of our services offered on our website at www.quniquegroup.com

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1. MDCG 2021-24: Guidance on classification of medical device. October 4, 2021.
2. EU Medical Device Regulations 2017/745. April 5, 2017.

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