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Classification of medical devices : The New MEDDEV Guidelines has just been published

In the Consultants Corner of last March, we sent a warning that Annex IX of the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC which places a special emphasis on a new definition of a device's time of use might lead to some reclassification of devices. The new classification guidelines MEDDEV 2. 4/1 Rev. 9 of June 2010, published 3 months after the enter in force of the amended MD directive (and not before as it should have been!) confirm this vision.
You will read below that for example, peripheral vascular catheter are considered as long term long-term surgically invasive devices in Rule 8, meaning a classification in IIb instead of IIa.
The Tracheal cannulae are now in class IIb (Rule 5), etc . .

There are some other important reclassifications given in the examples of the rules such as spinal needles which are now in class III instead of IIa because intended specifically for use in direct contact with the central nervous system (Rule 6)
We have made below a summary by rule which includes the most significant changes given in the examples of devices per class.

Rule 1 - Devices that either do not touch the patient or contact intact skin only: No change
Rule 2 - Channeling or storing for eventual administration: No significant change
Rule 3 – Non-invasive devices that modify biological or chemical composition of blood, body liquids or other liquids intended for infusion into the body: No change
Rule 4 - Non-invasive devices which come into contact with injured skin: No significant change

Rule 5 - Devices invasive with respect to body orifices
Class 1: Urinary catheters intended for transient use, Materials for manufacturing dentures (instead of dentures intended to be removed by the patient)
Class IIa: Short term corrective contact lenses - Indwelling urinary catheters intended for short term use
Class IIb: Long term corrective contact lenses, - Tracheal cannulae, - Urinary catheters intended for long term use

Rule 6 - Surgically invasive devices intended for transient use (< 60 minutes*)*
Class I: Reamers - Sternum retractors for transient use
Class IIa: No addition but the Trial hip prosthesis heads or stems have been removed from the examples as class 2a
Class III: stent delivery catheters/systems, Distal protection devices
Class III: (intended specifically for use in direct contact with the central nervous system) : Neuro-endoscopes, Brain spatulas, Direct stimulation canulae, Spinal cord retractors,
Spinal needles

Rule 7 - Surgically invasive devices intended for short-term use *(>60 minutes, <30 days)*
Class III: Ablation catheter

Rule 8 - Implantable devices and long-term surgically invasive devices (> 30 days)
Class IIa: No change for Bridges and crowns, - Dental filling materials and pins, - Dental alloys, ceramics and polymers
Class IIb: Prosthetic joint replacements not covered by Directive 2005/50/EC and valves (*e.g.* pulmonary), Internal closure devices.(including vascular closure devices) for closure of arteriotomies in the peripheral vascular system, Peripheral vascular catheters , Peripheral vascular grafts and stents.
Class III:

- to be used in direct contact with the heart, the central circulatory system or the central nervous system : Central vascular catheters, - Permanent and retrievable vena cava filters, - Septal occlusion devices, Intra-aortic balloon pumps, External left ventricular assisting devices
- Breast implants (Directive 2003/12/EC)
- Hip, knee and shoulder joint replacements and components of systems12 (Directive 2005/50/EC)

Rule 9 - Active therapeutic devices intended to administer or exchange energy: No change
Rule 10 - Active devices for diagnosis: No change
Rule 11 - Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body: No change

Rule 12 - All other active devices : Change: Removal of "Active devices intended for recording, processing or viewing of diagnostic images' in the examples of class 1.

Rule 13 - Devices incorporating, as an integral part, a medicinal product or a human blood derivative (See MEDDEV. 2.1/3 for further guidance)
Class III:
- Contraceptive intrauterine devices (IUDs) containing copper or silver
- Drug eluting stents, *e.g*. coronary, pulmonary
- Surgical sealants containing human serum albumin)

Rule 14 - Devices used for contraception or prevention of sexually transmitted diseases: No change

Rule 15 - Specific disinfecting, cleaning and rinsing devices

Class IIb: Devices that are specifically to be used for disinfecting invasive devices:
- Denture disinfecting products
- Washers-disinfectors for endoscopes
- Disinfectants for the fluid pathways of haemodialysis equipment
- Disinfectants for ocular prosthesis, intraosseous transcutaneous amputation prosthesis, surgical equipment and invasive dental equipment

Rule 16 - Devices to record X-ray diagnostic images: No significant change

Rule 17 - Devices utilising animal tissues or derivatives: Reference to MEDDEV 2.11/1 rev.2
Class III: Devices utilising hyaluronic acid of animal origin

Rule 18 - Blood bags: No significant change

You can find the complete new classification guidelines at:
http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf

Coming back to the new definition of a device's time of use, we can remark that the urinary catheters can be classified in 1, 2a or 2b following their intended indications given by the manufacturer in the IFU. However, if a manufacturer is aware that its urinary catheter will be often replaced by a similar device and the total potential device's time is more than 30 days, the notified body or a competent authority may ask for immediate reclassification in class IIb and with a risk of product put on hold!

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