Medical Devices and In-Vitro Diagnostics

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MD+IVDs, Market Authorization

Medical Device classification

➢ Risk based classification

➢ Classify Medical devices into four classes depending on the Risk.

➢ Classes are A,B,C&D

Medical Device classification

Class A   Low Risk

Class B   Low-moderate

Class C   Moderate-high

Class D   High Risk

Classification of Medical Devices with Examples

CLASS	RISK LEVEL	EXAMPLE
A	Low Risk	Cotton wool, urine collection bottles; hospital beds.
B	Low-moderate	Urinary catheters, tracheal tubes.
C	Moderate-high	contact lenses for long term continuous use,
D	High Risk	Pacemakers; Implantable defibrillators. prosthetic heart valves

Factors/Terms in MD classification

a. **Non-Invasive Medical Devices -** A device which in whole or in part does not penetrate the body, either through a body orifice or through the surface of the body

b. **Invasive Medical 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.

i. **Body orifice:** Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

ii. **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.

Terms/Factors

c. Active Medical Devices - any medical device relying for its functioning 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.

d. Exceptional Classes

i. Medical Devices which Incorporate Medicinal Substances

ii. Medical Devices- used for sterilizing or Disinfecting Medical Devices

iii. Medical Devices Incorporating Animal or Human Cells/Tissues/Derivatives

Terms continuation

iv. Medical Devices for Ophthalmic Solutions Use

v. Medical Devices for Contraception or the prevention of Sexually Transmitted Diseases' (STD's)

vi. Implantable Medical Devices for Long-term Use.

e. Duration of use

Transient use- Below 60 minutes.

Short term use- Between 60 minutes and 30 days.

Long term use - More than 30 days

Factors /Terms

NB: More than one class

a. Where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.

b. The actual classification of a Medical Device is determined by the Manufacturer and on its intended use.

CLASSIFICATION OF IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

Criteria classification of IVDs

1. The intended use and indications for use as specified by the manufacturer (specific disorder, condition or risk factor for which the test is intended)

2. The technical/scientific/medical expertise of the intended user (lay person or professional)

3. The importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician the impact of the result (true or false) to the individual and/or to public health

classification of IVD's and Examples

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser, prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Pregnancy self-testing, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self-testing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

THANK YOU

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