CLASSIFICATION CRITERIA FOR IN VITRO DIAGNOSTICS AND MEDICAL DEVICES ACCORDING TO NOVEL REGULATION [1, 2]

XENDO
SOLUTIONS FOR LIFE SCIENCES

IN VITRO DIAGNOSTICS

START

Rule 1
Devices intended to be used for the following purposes:

- 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;
- 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;
- determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.

Rule 2
Devices intended to be used for blood grouping, 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

except when intended to determine any of the following markers:
- ABO system;
- Rhesus system;
- Kell system;
- Kidd system;
- Duffy system;

Rule 3
Devices if they are intended:
- for detecting the presence of, or exposure to, a sexually transmitted agent
- for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;
- for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;
- for pre-natal screening of women in order to determine their immune status towards transmissible agents;
- for determining infective disease status or immune status, 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;

Rule 7
Devices ... are controls without ...itative or qualit... ...d value

... the ...tion

D The ... devices:
- p... or general laboratory ...essories which po... critical characteri... fer solutions, washing ... and general culture r... histological stain... d by the manufa... make them suitable... o diagnostic procedur... g to a specific ...ion;
- instru... ...ended by the manufac... ...ifically to be used f... diagnostic ...es;
- sp... ...ceptacles.

Rule 4
Devices intended for self-testing

except for 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

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

Rule 3 con't
- to be used as companion diagnostics;
- to be used for disease staging, 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;
- to be used in screening, diagnosis, or staging of cancer;
- for human genetic testing;
- 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;
- for management of patients suffering from a life-threatening disease or condition; - for screening for congenital disorders in the embryo or foetus;
- for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.
- for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

MEDICAL DEVICES

NON-INVASIVE

B
B
A
C
B
C
D
C

Rule 4
Non-invasive devices which come into contact with injured skin or mucous membrane (also applies to the invasive devices that come into contact with injured mucous membrane):

to be used as a mechanical barrier, for compression or for absorption of exudates; — I

OR
to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent; — IIB

OR
Principally intended to manage the micro-environment of injured skin or mucous membrane and all other cases. — IIA

Rule 3
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 — IIB

unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas or heat — IIA

OR
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 — III

Rule 2
Non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body:
if they may be connected to a class IIa, class IIb or class III active device; — IIA

OR
if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells & tissues. — IIA

OR
blood bags — IIB

Rule 1
Non-invasive devices unless one of the rules set out hereinafter applies. — I

INVASIVE

Rule 5
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:

if they are intended for transient use — I

OR
if they are intended for short-term use — IIA

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 — I

OR
if they are intended for long-term use — IIB

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 — IIA

OR
Invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device — IIA

Rule 6
Surgically invasive devices intended for transient use — IIA

unless
- are reusable surgical instruments — I

OR
- 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 — III
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system

OR
- are intended to supply energy in the form of ionising radiation — IIB
- have a biological effect or are wholly or mainly absorbed
- 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 hazardous taking account of the mode of application

Rule 8
Implantable d... ...es and long-term sur... ...nvasive (and anc... ...ponents such ... ...ges, plat... ...s) — IIB

- ... — IIA

- inter... ...ndergo chemical c... the body except if ... ...ces are place... ...eeth
- inten... used in direct cont... the heart, the central ... ...y system or the cent... ...s system
- have a ... effect or are wholly ... absorbed — III
- inten... ...minister medic... ...ucts
- active i... ...le devices or the ... ...ories,
- breast in... surgical

- total ... joint rep... ...ts
- spinal c... ...cement implants ... ...plantable devices ... ...e into contact with ... ...al column — IIA

Surgically ... devices intended f... ...erm use

- are inten... ...ifically to control, dia... ...nitor or correct a de... ...e heart or of the ce... ...ulatory system thro... ...ct contact with those ... the body — III
- are inten... ...fically for use in dire... ...t with the heart or c... ...culatory system or t... ...l nervous

- have a b... effect or are wholly ... absorbed

- are inte... supply energy in t... ...f ionizing ... — IIB
- are inte... ...ndergo chemical c... the body in which, ex... ...e devices are pla... teeth
- are inten... ...minister m...

ACTIVE

Rule 9
Active therapeutic devices intended to administer or exchange energy unless — IIA

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 — IIB

OR
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 Active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance — IIB

OR
Active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices — III

Rule 10
Active devices intended for diagnosis and monitoring — IIA

if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum — I

OR
if they are intended to image in vivo distribution of radiopharmaceuticals — IIB

if they are intended to allow direct diagnosis or monitoring of vital physiological processes, 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 — IIB

OR
Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance — IIB

Rule 13
All other active devices — I

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

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 — IIB

Rule 11
Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, — IIA

except if such decisions have an impact that may cause:

death or an irreversible deterioration of a person's state of health; — III

OR
a serious deterioration of a person's state of health or a surgical intervention — IIB

OR
Software intended to monitor physiological processes — IIA

except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient — IIB

OR
All other software — I

SPECIAL RULES

Devices ... integral pa... if used ... considere... product i... product ... blood or h... has an act... — III

Devices u... or prevent... of sexually ... — IIB

unless th... long ter... — III

Devices in... be use... cleanin... appropria... — IIB

Devices in... be use... sterilisi... — IIA

unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing — IIB

This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

Rule 17
Devices specifically intended for recording of diagnostic images generated by X-ray radiation. — IIA

Rule 18
Devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable — III

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.

...ting, as an ...tance which, ...y, can be ... medicinal ...a medicinal ...om human ...sma and that ...ary to that of ...es.

...ntraception ... transmission ...ted diseases

...plantable or ...e devices

...pecifically to ...nfecting, ...or, where ...ting contact

...pecifically to ...fecting or ...al devices

Rule 22
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 — III

Rule 21
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:

if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose; — III

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;

OR
if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities — IIA

OR
all other cases. — IIB

Rule 20
Invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation — IIA

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 — IIB

Rule 19
Devices incorporating or consisting of nanomaterial if they present a high or medium potential for internal exposure — III

OR
if they present a low potential for internal exposure — IIB

OR
if they present a negligible potential for internal exposure. — IIA

START

1. In case of final classification of your product, always consult the original text of MDR 2017/745 or IVDR 2017/746; no claims can be made in case of any error in the graph.
2. Revision 2017-05-29