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Important Definitions

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MDR references

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Key changes

Key changes

Number of definitions:

- MDD, article 1: 14 ➔ MDR, article 2: 71
- MDD, annex IX: 13 ➔ MDR, annex VIII: 11

Definitions moved from annex IX (MDD) to article 2 (MDR):

- invasive device
- implantable device
- active device (formerly active medical device)

Removed definitions:

- ‘in vitro diagnostic medical device’
- ’device subcategory’

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New and changed definitions

New definitions (1)

New general definitions:

- (9) ‘falsified device’
- (10) ‘procedure pack’
- (11) ‘system’
- (13) ‘label’
- (14) ‘instructions for use’ ← MEDDEV 2.14/3
- (15) ‘Unique Device Identifier’ (‘UDI’)

  ➔ *New Article 27 + Annex VI – UDI system*
- (16) ‘non-viable’
- (17) ‘derivative’

New definitions (2)

New definitions concerning nanomaterial:

- (18) ‘nanomaterial’
- (19) ‘particle’
- (20) ‘agglomerate’
- (21) ‘aggregate’

➔ *New classification rule 19: Nanomaterial*

New definitions (3)

New definitions:

- (22) ‘performance’
- (23) ‘risk’
- (24) ‘benefit-risk determination’
- (25) ‘compatibility’
- (26) ‘interoperability’
- (31) ‘fully refurbishing’

New definitions (4)

New definitions concerning market participants:

- (33) *'importer'*
- (34) *'distributor'*
- (35) 'economic operator'
- (36) 'health institution'
- (37) 'user' ← MEDDEV 2.12./1
- (38) 'lay person" ← MEDDEV 2.14/3
- (39) 'reprocessing" ← e.g. German Medical Devices Act

➔ *Article 13 - General obligations of importers*

➔ *Article 14 - General obligations of distributors*

New definitions (5)

New definitions concerning conformity assessment:

- (40) ‘conformity assessment’
- (41) ’conformity assessment body’
- (42) ’notified body’ ← e.g. German Medical Devices Act
- (43) ‘CE marking of conformity’ or ‘CE marking’

New definitions (6)

New definitions concerning clinical evaluation / investigation:

- (44) ‘clinical evaluation’ ← MEDDEV 2.7./1
- (45) ’clinical investigation’ ← MEDDEV 2.7./1
- (47) ’clinical investigation plan“ ← MEDDEV 2.7./1
- (49) ‘sponsor’ ← e.g. German Medical Devices Act
- (50) ‘subject’ (in the context of clinical investigations)
- (51) ‘clinical evidence’ ← MEDDEV 2.7/1
- (52) ‘clinical performance’ ← MEDDEV 2.7/1
- (53) ‘clinical benefit’
- (54) ‘investigator’
- (55) ‘informed consent’
- (56) ‘ethics committee’

New definitions (7)

New definitions concerning market surveillance (1)

- (57) ‘adverse event‘ ← MEDDEV 2.7/1
- (58) ‘serious adverse event“ ← MEDDEV 2.7/1
- (59) ‘device deficiency‘ ← MEDDEV 2.7/3
- (60) ‘post market surveillance“ ← 21 CFR part 822
- (61) ‘market surveillance’
- (62) ‘recall’
- (63) ‘withdrawal’
- (64) ‘incident’ ← MEDDEV 2.12/1
- (65) ‘serious incident’
- (66) ‘serious public health threat’ ← MEDDEV 2.12/1

New definitions (8)

New definitions concerning market surveillance (2):

- (67) ‘corrective action’ ← MEDDEV 2.12/1
- (68) ‘field safety corrective action’ ← MEDDEV 2.12/1
- (69) ‘field safety notice’ ← MEDDEV 2.12/1

New definitions (9)

More new definitions:

- (70) ‘harmonised standard’
- (71) ‘common specifications’

  ➔ *Article 9 - common specifications*

- ‘Injured skin or mucous membrane’ (annex VIII)

  ➔ *changed classification rule 4*

New definitions (10)

New definition *'making available on the market'* in addition to „**placing on the market**"

When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, the operation is always labelled in legal terms as '**placing on the market**'.

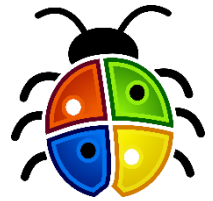
Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.
('Blue Guide' on the implementation of EU products rules 2016)

Removed definitions

Removed definition ‘device subcategory‘

Art. 52 (6) MDR: Manufacturers of class IIa devices, ..., shall be subject to a conformity assessment ... and including an assessment of the technical documentation ... of at least one representative device for *each category of devices*.

➔ *‘category of devices’ is not defined (a bug???)*



Removed definition ’in vitro diagnostic medical device’

➔ *no longer needed for the scope of MDR*

Changed definitions (1)

'medical device' means any instrument, apparatus, appliance, software, *implant, reagent,* material or other article .... of the following specific medical purposes:

- diagnosis, prevention, monitoring, *prediction, prognosis*, treatment or alleviation of disease,

  ...
- 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,*

Changed definitions (2)

'medical device' ....

The following products shall also be deemed to be medical devices:

- *devices for the control or support of contraception;*
- *products specifically intended for the cleaning, disinfection or sterilisation of devices ....*

Changed definitions (3)

'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) *or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)*;

Changed definitions (4)

‘custom made device’ .....

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user *and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person* shall not be considered to be custom-made devices;

➔ *e.g. industrial manufactured compression stockings*

Changed definitions (5)

‘intended purpose’ means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use *or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;*

Changed definitions (6)

‘authorised representative’ means any natural or legal person established within the Union *who has received and accepted a written mandate from a manufacturer, located outside the Union,* to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation

Changed definitions (7)

'clinical data' means information concerning safety or performance that is generated ...

- reports published *in peer reviewed scientific literature* on other clinical experience .....
- *clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;*