

Newly Updated European Classification Guidance

Determining the appropriate classification of a medical device is critically important. All manufacturers marketing devices in Europe should refer to a newly updated European guidance document on device classification.

MDD revisions on classification

Revising Directive 2007/47/EC¹, which was published on 21 September 2007, amended the Medical Devices Directive (93/42/EEC; MDD) and the Active Implantable Medical Devices Directive (90/385/EEC; AIMDD), but not the In Vitro Diagnostic Medical Devices Directive (98/79/EC; IVDD). These amendments became mandatory on 21 March 2010, which means that any medical devices covered by these directives that were placed on the market or put into service on or after that date must comply with the revised MDD and AIMDD. This article discusses the newly revised European guidance document, or MEDDEV, on classification², which applies to devices subject to the MDD.

The amendments to the MDD related to classification are summarised in Table I and include revisions to Article 9, Classification, and Annex IX, Classification Criteria. In Annex IX, revisions were made to the definition of vessels that mean the central circulatory system, the interpretation of “continuous use,” and Rules 5, 6, 7 and 13. The newly revised MEDDEV on classification takes these changes into account.

Revised format and content

The revised MEDDEV on classification replaces the earlier version published in July 2001. This is an important revision, covering not only amendments related to classification from revising Directive 2007/47/EC, but also those resulting from directives issued since the last revision, which reclassified breast implants and hip, knee and shoulder joint replacements, and specified requirements for devices containing human blood derivatives and devices manufactured utilising tissues of animal origin. Other changes have been made based upon experience gained from publication of the last version of the document and to improve clarity.

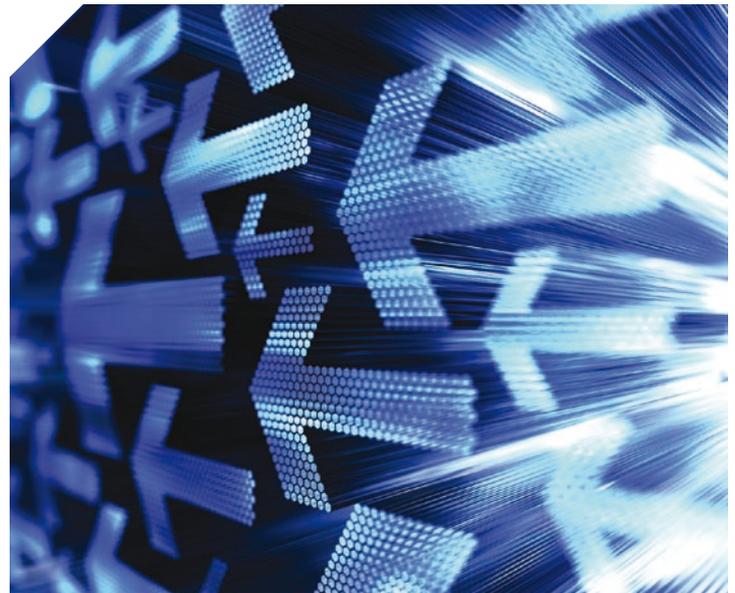


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Some structural changes also have been introduced. In the July 2001 version, the document was composed of two separate documents. Part 1 was 17 pages and included all sections except section 4.2, “General explanation of rules/practical issues/examples.” Part 2 was 41 pages and consisted of section 4.2. The updated guidance document combines both parts into a single 51-page document, which is easier to manage. The table of contents is very similar to the previous version; however, section 2.3 is now titled “Clinical evaluation and investigation” instead of “Clinical data;” section 2.4 is titled “Instructions for use” instead of “Labelling;” section 3.2 is titled “Application of the classification rules” instead of “Application rules;” and section 3.3 is revised to “How to use the rules” instead of “How to use the rules and the decision tree.”



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Table I: Amendments to the Medical Devices Directive (93/42/EEC) related to classification

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| Article 9, Classification | Revises the procedure that member states and the European Commission must follow for amending nonessential elements of the MDD relating to adaptation of classification rules. |
| Annex IX, Chapter I. Definitions, Section 1.7 | Added arcus aorta and aorta descendens to the bifurcatio aortae to the list of vessels that mean the “central circulatory system.” |
| Annex IX, Chapter II. Implementing Rules, Section 2.6 | Added clarification on calculating the duration referred to in Section 1.1 of Chapter I, such that continuous use means “an uninterrupted actual use of the device for the intended purpose.” However, if usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device, this shall be considered an extension of the continuous use of the device. |
| Annex IX, Chapter III. Classification, Section 2.1, Rule 5 | Added to Rule 5: invasive devices with respect to body orifices, other than surgically invasive devices, which are intended for connection to an active medical device in Class I. |
| Annex IX, Chapter III. Classification, Section 2.2, Rule 6 | Added to Rule 6: devices intended specifically to control a defect of the heart or central circulatory system through direct contact with these parts of the body to the list of surgically invasive devices intended for transient use, which are in Class III. |
| Annex IX, Chapter III. Classification, Section 2.3, Rule 7 | Added to Rule 7: devices intended specifically to control a defect of the heart or central circulatory system through direct contact with these parts of the body to the list of surgically invasive devices intended for short-term use, which are in Class III. |
| Annex IX, Chapter III. Classification, Section 4.1, Rule 13 | Updated the Medicinal Products Directive reference from Directive 65/65/EEC to Directive 2001/83/EC with regard to devices incorporating an integral part, a substance, which, if used separately, can be considered to be a medicinal product that is liable to act on the human body with action ancillary to that of the devices. |

➔ The information on the purpose and philosophy of medical device classification in section 1 is also similar to the previous version, but the text is more concise and improved. In addition, it points out that the classification rules in Annex IX of the MDD correspond to a large extent to the classification rules established by the Global Harmonization Task Force (GHTF) in guidance document GHTF/SG1/N 15:2006, obtainable from the GHTF website at www.ghtf.org/sg1/sg1-final.html.

Revisions related to Directive 2007/47/EC

As in the previous version, a helpful table in section 2.2, “Conformity assessment,” shows the relationship between the various device classes and the choice of conformity assessment procedures available to the manufacturer. Readers will note that the table has been modified to indicate that manufacturers of Class I sterile devices and devices with a measuring function must observe one of the procedures outlined in Annex II (minus section 4), IV, V or VI instead of only Annex IV, V or VI, as specified in the previous guidance document. This is because revising Directive 2007/47/EC modified section 5 of Annex VII, EC Declaration of Conformity, to allow the use of Annex II.

Section 2.3, “Clinical evaluation and investigation,” has been modified to take into consideration important amendments to the MDD related to new and clarified requirements on clinical data specified by Directive 2007/47/EC. This section points out that, as part of the Essential Requirements, a clinical evaluation in accordance with Annex X must be conducted for all medical devices. It also refers to the requirement in Annex X that, as a general rule, confirmation of conformity with sections 1 and 3 of Annex I of the MDD must be based on clinical data. In addition, in accordance with Annex X, section 1.1a, in the case of implantable devices and Class III devices clinical investigations must be performed unless it

is duly justified that existing clinical data are sufficient.

Section 3.1.2.2, “Concept of continuous use,” discusses section 2.6 of Chapter II of Annex IX of the MDD, which was added by Directive 2007/47/EC, as previously discussed. The example of a scalpel as a transient use device is the same example provided in the previous version of the guidance document. However, a new statement adds clarification: if it cannot be demonstrated that components of the device are totally eliminated in the interval between uses, this is also considered an immediate replacement.

Helpful clarifications

Section 3.1.3, “Invasiveness,” includes two new guidance statements. The first states that the term “surgical operation” used in the definition of “surgically invasive device” includes all clinical interventional procedures in which a device is placed into the body through the surface in the context of a surgical operation or other clinical procedure. The second states that the concept of surgically invasive should be understood also to cover liquids that are in invasive contact with organs, tissue or other parts of the body if the access for such liquids is through a surgically created opening. The definitions of central circulatory system and central nervous system taken from Annex IX of the MDD have also been added to this section since they are critical anatomical locations that affect device classification.

A new section 3.1.6, “Procedure packs,” provides guidance on classification of a procedure pack incorporating devices that do not bear the CE mark. The guidance states that the classification for a procedure pack that is a device in its own right is normally determined by the intended use. The guidance further states that in cases where the intended use of the procedure pack is not specific enough to determine classification, the classification of the pack is at the level of the highest classified device included in the pack.

Readers interested in this issue should refer to the full text of the guidance document.

Section 3.3, "How to use the rules," includes new advice on the need for manufacturers to take account of additional directives that may affect the classification of their device or the conformity route to be followed. These include:

- Directive 2003/12/EC7 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices
- Directive 2005/50/EC8 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices
- Directive 2003/32/EC9 introduces detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin.

Managing classification questions

In addition to advice provided in the previous version of the classification guidance document, Section 3.5, "Handling of interpretational problems," has been expanded to include a statement that complex classification issues may be referred to the Borderline and Classification Medical Devices Expert Group for resolution. In addition, it points out that MEDDEV 2.1/3 rev 311 provides useful

information relating to devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product or a human blood derivative, and that is liable to act on the human body with action ancillary to that of the devices.

Guidance charts and device examples

The flow charts providing a quick reference to classification, which should always be confirmed by reading the rules, and the tabular presentation of the classification rules with device examples, have been retained in the guidance document. Where necessary, changes have been made to address classification revisions resulting from revising Directive 2007/47/EC and the other amending or implementing directives affecting device classification under the MDD. ☺

References

1. Directive 2007/47/EC can be obtained from the European Commission website: http://ec.europa.eu/enterprise/sectors/medical-devices/index_en.htm
2. *Medical Devices: Guidance document, Classification of medical devices (MEDDEV 2.4/1 Rev. 9, June 2010)*: http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf

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