New Regulations


**Guidance documents to the new regulations**

<table>
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<th>Title</th>
<th>Document</th>
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<tr>
<td><strong>2.1 Scope, field of application, definition</strong></td>
<td>MEDDEV 2.1/1 (18 kB) Definitions of “medical devices”, “accessory” and “manufacturer” April 1994</td>
</tr>
<tr>
<td></td>
<td>MEDDEV 2.1/2 rev.2 (14 kB) Field of application of directive “active implantable medical devices” April 1994</td>
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<td></td>
<td>MEDDEV 2.1/2.1 (12 kB) Treatment of Computers Used to Program Implantable Pulse Generators February 1998</td>
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<td></td>
<td>MEDDEV 2.1/3 rev.3 (183 kB) Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative December 2009</td>
</tr>
<tr>
<td></td>
<td>MEDDEV 2.1/4 (21 kB) Interface with other directives – Medical devices/directive 89/336/EEC relating to electromagnetic compatibility and directive 89/686/EEC relating to personal protective equipment March 1994</td>
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<tr>
<td></td>
<td>MEDDEV 2.1/5 (10 kB) Medical devices with a measuring function June 1998</td>
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<td>MEDDEV 2.1/6 (514 kB) Qualification and Classification of stand alone software July 2016</td>
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<td><strong>2.2 Essential requirements</strong></td>
<td>MEDDEV 2.2/1 rev.1 (16 kB) EMC requirements February 1998</td>
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<td>MEDDEV 2.2/3 rev.3 (17 kB) “Use by”-date June 1998</td>
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<td>MEDDEV 2.2/4 (38 kB) Conformity assessment of In Vitro Fertilisation (IVF) and Assisted Reproduction Technologies (ART) products January 2012</td>
</tr>
<tr>
<td><strong>2.4 Classification of MD</strong></td>
<td>MEDDEV 2.4/1 rev.9 (759 kB) Classification of medical devices June 2010</td>
</tr>
<tr>
<td><strong>2.5 Conformity assessment procedure</strong></td>
<td>General rules</td>
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</table>
Quality assurance.
Regulatory auditing of quality systems of medical device manufacturers
(See document in the GHTF-Global Harmonization Task Force)
MEDDEV 2.5/3 rev.2 (8 kB) Subcontracting quality systems related
June 1998
MEDDEV 2.5/5 rev.3 (7 kB) Translation procedure
February 1998
MEDDEV 2.5/6 rev.1 (9 kB) Homogenous batches (verification of manufacturers’
products)
February 1998
Conformity assessment for particular groups of products
MEDDEV 2.5/7 rev.1 (92 kB) Conformity assessment of breast implants
July 1998
MEDDEV 2.5/9 rev.1 (96 kB) Evaluation of medical devices incorporating products
containing natural rubber latex
February 2004
MEDDEV 2.5/10 (80 kB) Guideline for Authorised Representatives
January 2012

2.7
Clinical investigation, clinical evaluation
MEDDEV 2.7/1 rev.4 (631 kB) Clinical evaluation: Guide for manufacturers and
notified bodies
June 2016
Appendix 1: Clinical evaluation on coronary stents (100 kB)
December 2008
MEDDEV 2.7/2 rev.2 (412 kB) Guidelines for Competent Authorities for making a
validation/assessment of a clinical investigation application under directives
90/385/EEC and 93/42/EC
September 2015
MEDDEV 2.7/3 rev.3 (383 kB) Clinical investigations: serious adverse reporting under
directives 90/385/EEC and 93/42/EC - SAE reporting form (27 kB)
May 2015

The new SAE reporting form will be taken in use 1 September 2016 at the latest.
MEDDEV 2.7/4 (183 kB) Guidelines on Clinical investigations: a guide for
manufacturers and notified bodies
December 2010

The documents on designation of notified bodies under the new Regulations are in
the section above (MDCG documents)
MEDDEV 2.10/2 rev.1 (105 kB) Designation and monitoring of Notified Bodies within
the framework of EC Directives on Medical devices
Annex 1 (119 kB), Annex 2 (14 kB), Annex 3 (16 kB), Annex 4 (26 kB)
April 2001
MEDDEV 2.12/1 rev.8 (763 kB)
Guidelines on a Medical Devices Vigilance System
January 2013

2.12
Market surveillance
MEDDEV 2.12/1 rev.8 – Latest Version Forms
MEDDEV 2.12/1 rev. 7 MIR and FSCA are still valid

Active PDF forms
How to use FSCA and MIR forms (12 kB)
Manufacturer Incident Report - MIR (971 kB)
Field Safety Corrective Action - FSCA (1 MB)
MIR and FSCA xml files
Please note: Some browser plugins are not compatible with PDF forms. If you have problems opening these forms, please save them to your computer and open them from there.

Other forms and templates
Field Safety Notice Template (27 kB)
Trend Report (151 kB)
Periodic Summary Report (192 kB)

II. Device Specific Vigilance Guidance

DSVG Template (22 kB)
DSVG 00 (20 kB) Introduction to Device Specific Vigilance Guidance
DSVG 01 (24 kB) Cardiac Ablation Vigilance Reporting Guidance
DSVG 02 (26 kB) Coronary Stents Vigilance Reporting Guidance

2.13 Transitional period
MEDDEV 2.12/2 rev.2 (228 kB) Post Market Clinical Follow-up studies
January 2012
MEDDEV 2.13 rev.1 Commission communication on the application of transitional provision of Directive 93/42/EEC relating to medical devices (OJ 98/C 242/05)
August 1998
As regards the transitional regime of Directive 2007/47/EC see the Interpretative Document of the Commission’s services of 5 June 2009 (35 kB)

2.14 IVD
MEDDEV 2.14/2 rev.1 (64 kB) Research Use Only products
February 2004
MEDDEV 2.14/3 rev.1 (80 kB) Supply of Instructions For Use (IFU) and other information for In-vitro Diagnostic (IVD) Medical Devices
January 2007
Form for the registration of manufacturers and devices In Vitro Diagnostic Medical Device Directive, Article 10 (213 kB)
January 2007
MEDDEV 2.14/4 (114 kB) CE marking of blood based in vitro diagnostic medical devices for vCJD based on detection of abnormal PrP
January 2012

2.15 Other guidances
MEDDEV 2.15 rev.3 (32 kB) Committees/Working Groups contributing to the implementation of the Medical Device Directives
December 2008

European Competent Authorities for Medical Devices
https://www.camd-europe.eu/

MDR and IVDR Transitional FAQs https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/

Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap

Notified Bodies

List of EU Notified Bodies

http://www.nbog.eu/nbog-documents/

Designation of notified bodies under the new Regulations on medical devices

<table>
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<tr>
<th>Notified BODIES</th>
<th>Designation of notified bodies under the new Regulations on medical devices</th>
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<tr>
<td></td>
<td>1. Best practice guidance on designation and notification of conformity assessment bodies (NBOG BPG 2017-1)</td>
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<td>2. Best practice guidance on the information required for conformity assessment bodies' personnel involved in conformity assessment activities (NBOG BPG 2017-2)</td>
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<tr>
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<td>3. Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices Regulation (MDR) (NBOG F 2017-1)</td>
</tr>
<tr>
<td></td>
<td>4. Application form to be submitted by a conformity assessment body when applying for designation as notified body under the in vitro diagnostic devices Regulation (IVDR) (NBOG F 2017-2)</td>
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<tr>
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<td>7. Preliminary assessment review template (MDR) (NBOG F 2017-5)</td>
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<tr>
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<td>8. Preliminary assessment review template (IVDR) (NBOG F 2017-6)</td>
</tr>
<tr>
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<td>9. Review of qualification for the authorisation of personnel (MDR) (NBOG F 2017-7)</td>
</tr>
<tr>
<td></td>
<td>10. Review of qualification for the authorisation of personnel (IVDR) (NBOG F 2017-8)</td>
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</tbody>
</table>

MHRA Guidance to Notified Bodies

Nomenclature and UDI

Publication of first UDI guidance and requirements for medical device nomenclature: March 2018

<table>
<thead>
<tr>
<th>Reference</th>
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<tbody>
<tr>
<td>MDCG 2018-1</td>
<td>Draft guidance on basic UDI-DI and changes to UDI-DI</td>
<td>March 2018</td>
</tr>
<tr>
<td>MDCG 2018-2</td>
<td>Future EU medical device nomenclature – Description of requirements</td>
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</table>

Safety

Adverse event reporting from clinical investigations https://ec.europa.eu/growth/sectors/medical-devices/guidance_en
Mandate to SCHEER to produce guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting properties.


**Other resources and news**

Value and Use of Patient Reported Outcomes in in Assessing Effects of Medical Devices


Software als Medizinprodukt (German)

http://www.xing-news.com/reader/news/articles/1472724?cce=em5e0cbb4d.%3Auyu72CakZNu7uDIDUTPbAP&link_position=digest&newsletter_id=34464&toolbar=true&xng_share_origin=email

A New Era for Medical Devices: Current Regulatory Issues


Resource library for medical device professionals (EMERGO)

https://www.emergobyul.com/resources

BSI Medical devices Resources white papers series