European Commission

EC Medical Devices Unit https://ec.europa.eu/growth/sectors/medical-devices_en

New Regulations

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Guidance documents to the new regulations

	Title
2.1 Scope, field of application, definition	MEDDEV 2.1/1 (18 kB) Definitions of "medical devices", "accessory" and "manufacturer" **April 1994**
	MEDDEV 2.1/2 rev.2 (14 kB) Field of application of directive "active implantable medical devices" **April 1994**
	MEDDEV 2.1/2.1 (12 kB) Treatment of Computers Used to Program Implantable Pulse Generators **February 1998**
	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**
	MEDDEV 2.1/4 (21 kB) Interface with other directives – Medical devices/directive89/336/EEC relating to electromagnetic compatibility and directive 89/686/EEC relating to personal protective equipment **March 1994** For the relation between the MDD and directive 89/686/EEC concerning personal protective equipment, please see the Commission services interpretative document of 21 August 2009 (28 kB)
	MEDDEV 2.1/5 (10 kB) Medical devices with a measuring function **June 1998**
	MEDDEV 2.1/6 (514 kB) Qualification and Classification of stand alone software **July 2016**
2.2 Essential requirements	MEDDEV 2.2/1 rev.1 (16 kB) EMC requirements **February 1998**
	MEDDEV 2.2/3 rev.3 (17 kB) "Use by"-date **June 1998**
	MEDDEV 2.2/4 (38 kB) Conformity assessment of *In Vitro* Fertilisation (IVF) and Assisted Reproduction Technologies (ART) products **January 2012**
2.4 Classification of MD	MEDDEV 2.4/1 rev.9 (759 kB) Classification of medical devices **June 2010**
2.5 Conformity assessment procedure	**General rules**

	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**
2.10 Notified bodies	**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**
2.12 **Market surveillance**	MEDDEV 2.12/1 rev.8 (763 kB) Guidelines on a Medical Devices Vigilance System **January 2013** Ⅰ. **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
	MEDDEV 2.12/2 rev.2 (228 kB) Post Market Clinical Follow-up studies **January 2012**
2.13 Transitional period	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 2.14/1 rev.2 (76 kB) Borderline and Classification issues. A guide for manufacturers and notified bodies **January 2012**
	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 https://www.camd-europe.eu/regulatory/medical-devices-regulation-vitro-diagnostics-regulation-mdr-ivdr-roadmap/

Joint Action on Market Surveillance of Medical Devices (JAMS) https://www.camd-europe.eu/joint-action-projects/market-surveillance-of-medical-devices-jams/

Notified Bodies

List of EU Notified Bodies
http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main

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

Designation of notified bodies under the new Regulations on medical devices

Notified BODIES	Designation of notified bodies under the new Regulations on medical devices
	1. Best practice guidance on designation and notification of conformity assessment bodies (NBOG BPG 2017-1) 2. Best practice guidance on the information required for conformity assessment bodies' personnel involved in conformity assessment activities (NBOG BPG 2017-2) 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) 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) 5. Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR) (NBOG F 2017-3) 6. Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR) (NBOG F 2017-4) 7. Preliminary assessment review template (MDR) (NBOG F 2017-5) 8. Preliminary assessment review template (IVDR) (NBOG F 2017-6) 9. Review of qualification for the authorisation of personnel (MDR) (NBOG F 2017-7) 10. Review of qualification for the authorisation of personnel (IVDR) (NBOG F 2017-8)

MHRA Guidance to Notified Bodies
https://www.gov.uk/government/publications/notified-bodies-for-medical-devices/notified-bodies-for-medical-devices

Nomenclature and UDI

Publication of first UDI guidance and requirements for medical device nomenclature: March 2018
https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

Reference	Title	Publication date
MDCG 2018-1	Draft guidance on basic UDI-DI and changes to UDI-DI	March 2018
MDCG 2018-2	Future EU medical device nomenclature – Description of requirements	

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
https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_q_009.pdf

Other resources and news

Value and Use of Patient Reported Outcomes in in Assessing Effects of Medical Devices
https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM588576.pdf

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
https://globalforum.diaglobal.org/issue/june-2018/a-new-era-for-medical-devices/?_ga=2.150857974.1720312607.1534013672-1287427849.1534013672

Resource library for medical device professionals (EMERGO)
https://www.emergobyul.com/resources

BSI Medical devices Resources white papers series
https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/