Guidance MEDDEVs

The MEDDEVs promote a common approach to be followed by manufacturers and notified bodies that are involved in conformity assessment procedures.

- The MEDDEVs are drafted by authorities charged with safeguarding public health in conjunction with all stakeholders (industry associations, health professionals associations, notified bodies and European standardisation organisations). This is in accordance with the relevant annexes of the directives
- MEDDEVs are carefully drafted through a consultation process with all interested parties and are subject to a regular updating process
- These documents have particular reference codes and are endorsed at the medical devices expert group (MDEG) plenary meetings
- The guidelines are not legally binding. However, due to the participation of the aforementioned interested parties and the experts from competent authorities, it is expected that the guidelines be followed, ensuring the uniform application of relevant directive provisions.

Disclaimer: Please note that the amendments introduced by Directive 2007/47/EC or previous amending directives have not yet been incorporated into all MEDDEVs.

List of guidance MEDDEVs

See below a complete list of all guidance MEDDEVs, including links to further information:

	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**

	Title
	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 Directive 89/336/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 was taken in use by 1 September 2016.**
	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 Post-Market surveillance	MEDDEV 2.12/1 rev.8 (763 kB) Guidelines on a medical devices vigilance system **January 2013** Additional guidance on MEDDEV 2.12/1 rev.8 (855 kB) **July 2019** **Ⅰ. MEDDEV 2.12/1 rev.8** – Latest Version Forms MEDDEV 2.12 rev. 7 FSCA is still valid **Active PDF forms**

	New MIR form* - as from January 2020 New manufacturer incident report (PDF form) New manufacturer incident report for importing XML file* with Adobe Professional The published MIR form is password-protected so it may be necessary to unlock it for specific purposes (e.g. translating the form, implementing it into in-house IT systems). You can request the password for specific authorised uses, which are subject to terms and conditions. New manufacturer incident report XSD file and XSL files (for implementation in manufacturer' databases) New manufacturer incident report help text Changelog file Questions and answers document on the implementation of the new MIR form *If you're a manufacturer and have already adapted your IT system to version 7.2, you may use this version until the end of March 2020. 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 corrective action - FSCA (1 MB) FSCA xml files Field safety notice template (105 kB) FSN customer reply (108 kB) FSN distributor/importer reply (103 kB) FSN Q&A (152 kB) Trend report (151 kB) Periodic summary report (192 kB) **Ⅱ. Device specific vigilance guidance** DSVG Template DSVG 00 Introduction to device specific vigilance guidance DSVG 01 Cardiac ablation vigilance reporting guidance DSVG 02 Coronary stents vigilance reporting guidance DSVG 03 Cardiac implantable electronic devices (CIED) DSVG 04 Breast implants DSVG 05 Insulin Infusion Pumps and Integrated meter systems
	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 guidance	MEDDEV 2.15 rev.3 (32 kB) Committees/working groups contributing to the implementation of the medical device directives **December 2008**