Raccolta linee guida MEDDEV e MDCG dispositivi medici

Update Settembre 2023
(28.09.2023)

Certifico Srl - IT

ID 2047 | Update Rev. 33.0 2023 (28.09.2023)

Allegate tutte le Guide ufficiali sui i Dispositivi medici in accordo con la Direttiva 93/42/CEE e il nuovo Regolamento (UE) 2017/745

Direttiva 93/42/CEE del Consiglio del 14 giugno 1993 concernente i dispositivi medici(*)

(*) Direttiva abrogata e sostituita dal Regolamento (UE) 2017/745 | Si applica dal 20 Maggio 2020

New regulations

Guidance documents to assist stakeholders in implementing the Medical Devices Regulations.

1. MDCG Documents

MDCG endorsed documents

Reference	Title	Publication date
MDCG 2023-3	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices	Febraury 2023
MDCG 2023-2 MDR form	List of Standard Fees	January 2023
MDCG 2023-2 IVDR form	List of Standard Fees	January 2023
MDCG 2023-2	List of Standard Fees	January 2023
MDCG 2023-1	Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	January 2023
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745	December 2022
MDCG 2022-20	Substantial modification of performance study under Regulation (EU) 2017/746	December 2022
MDCG 2022-19	Performance study application/notification documents under Regulation (EU) 2017/746	December 2022
Q&A Rev. 1	Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the "sell off" periods	July 2023
MDCG 2022-18 ADD.1	MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate - Addendum 1	June 2023
MDCG 2022-18	MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate	December 2022
MDCG 2022-17	MDCG position paper on "hybrid audits"	December 2022
MDCG 2022-16	Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2022
MDCG 2022-15	Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD	September 2022

MDCG 2022-14	Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs	August 2022
MDCG 2022-13	Designation, re-assessment and notification of conformity assessment bodies and notified bodies	August 2022
MDCG 2022-12	MDCG 2022-12 Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)	July 2022
MDCG 2022-11	MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements	May 2022
MDCG 2022-10	Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)	May 2022
MDCG 2022-9	Summary of safety and performance template	May 2022
MDCG 2022-8	Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC	May 2022
MDCG 2022-7	Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)	May 2022
MDCG 2022-6	Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR	May 2022
MDCG 2022-5	Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical	May 2022
MDCG 2022-4 rev.1	Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD	December 2022
MDCG 2022-4	Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR	February 2022
MDCG 2022-3	Verification of manufactured class D IVDs by notified bodies	February 2022
MDCG 2022-2	Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)	January 2022
MDCG 2022-1	Notice to 3rd country manufacturers of SARS-CoV-2 in vitro diagnostic medical devices	January 2022
MDCG 2021-28	Substantial modification of clinical investigation under Medical Device Regulation	December 2021
MDCG 2021-27	Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	December 2021
MDCG 2021-26	Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2021
MDCG 2021-25	Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC	October 2021
MDCG 2021-24	Guidance on classification of medical devices	October 2021
Helsinki Procedure	Helsinki Procedure for borderline and classification under MDR & IVDR	September 2021

MDCG 2021-23	Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	August 2021
MDCG 2021-22	Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746	August 2021
MDCG 2021-21	Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices	August 2021
MDCG 2021-20	Instructions for generating CIV-ID for MDR Clinical Investigations	July 2021
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system	July 2021
MDCG 2021-18	Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR)	July 2021
MDCG 2021-17	Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR)	July 2021
MDCG 2021-16	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)	July 2021
MDCG 2021-15	Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR)	July 2021
MDCG 2021-14	Explanatory note on IVDR codes	July 2021
MDCG 2021-13 Rev. 1.0	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR	July 2021
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)	June 2021
MDCG 2021-11	Guidance on Implant Card – Device types	May 2021
MDCG 2021-10	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices	May 2021
MDCG 2021-9	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers	May 2021
MDCG 2021-8	Clinical investigation application/notification documents	May 2021
MDCG 2021-7	Notice to manufacturers and authorised representatives on the impact of genetic variants on SARS-COV-2 in vitro diagnostic medical devices	May 2021
MDCG 2021-6	Regulation (EU) 2017/745 - Questions & Answers regarding clinical investigation	April 2021
MDCG 2021-5	Guidance on standardisation for medical devices	April 2021
MDCG 2021-4	Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746	April 2021
MDCG 2021-3	Questions and Answers on Custom-Made Devices	March 2021
MDCG 2021-2	Guidance on state of the art of COVID-19 rapid antibody tests	March 2021

MDCG 2021-1	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional	Febraury 2021
MDCG 2020-18	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers	December 2020
MDCG 2020-17	Questions and Answers related to MDCG 2020-4: "Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions"	December 2020
MDCG 2020-16 Rev.2	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	Febraury 2023
MDCG 2020-16	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	November 2020
MDCG 2020-15	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States	August 2020
MDCG 2020-14	Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR)	August 2020
MDCG 2020-13	Clinical evaluation assessment report template	July 2020
MDCG 2020-12	Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues	June 2020
MDCG 2020-11	Guidance on the renewal of designation and monitoring of notified bodies under Directives 90/385/EEC and 93/42/EEC to be performed in accordance with Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation	May 2020
MDCG 2020-10-2	Clinical Investigation Summary Safety Report Form v1.0	May 2020
MDCG 2020-10-1	Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745	May 2020
MDCG 2020-9	MDCG 2020-9 Regulatory requirements for ventilators and related accessories	April 2020
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template	April 2020
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template	April 2020
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	April 2020
MDCG 2020-5	Clinical Evaluation - Equivalence	April 2020
MDCG 2020-4	Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions	April 2020
MDCG 2020-3 Rev.1	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD	September 2023
MDCG 2020-3	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD	March 2020
MDCG 2020-2	Class I Transitional provisions under Article 120 (3 and 4) – (MDR)	March 2020
MDCG 2020-1	Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software	March 2020
MDCG 2019-16	Guidance on Cybersecurity for medical devices	December 2019
MDCG 2019-15	Guidance notes for manufacturers of class I medical devices	December 2019
MDCG 2019-14	Explanatory note on MDR codes	December 2019

MDCG 2019-13	Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation	December 2019
MDCG 2019-12	Designating authority's final assessment form: Key information (EN)	October 2019
MDCG 2019-11	Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2019
MDCG 2019-10	Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC	October 2019
MDCG 2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies	August 2019
MDCG 2019-8 v2	Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	March 2020
MDCG 2019-8	Medical Devices: Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	July 2019
MDCG 2019-7	Guidance on Article 15 of the Medical Device Regulation (MDR) and in vitro Diagnostic Device Regulation (IVDR) regarding a 'person responsible for regulatory compliance' (PRRC)	June 2019
MDCG 2019-6 v3	Questions and answers: Requirements relating to notified bodies	October 2021
MDCG 2019-5	Registration of legacy devices in EUDAMED	April 2019
MDCG 2019-4	Timelines for registration of device data elements in EUDAMED	April 2019
MDCG 2019-3	Interpretation of Article 54(2)b Rev.1	April 2020
MDCG 2019-2	Guidance on application of UDI rules to device-part of products referred to in Article 1(8), 1(9) and 1(10) of Regulation 745/2017	February 2019
MDCG 2019-1	MDCG guiding principles for issuing entities rules on Basic UDI-DI	January 2019
MDCG 2018-1 v3	Guida su UDI-DI di base e modifiche a UDI-DI	March 2020
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	March 2018
MDCG 2018-3	Guidance on UDI for systems and procedure packs	October 2018
MDCG 2018-4	Annex: UDI database Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs	October 2018
MDCG 2018-5	UDI Assignment to Medical Device Software	October 2018
MDCG 2018-6	Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation (EU) 2017/745 and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746	October 2018
MDCG 2018-7	Provisional considerations regarding language issues associated with the UDI database (Annex VI, Part A Section 2 and Part B of the Medical Device Regulation (EU) 2017/745 (MDR) and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR))	October 2018

MDCG 2018-8	Guidance on content of the certificates, voluntary certificate transfers	November 2018

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)

Other documents

Reference	Title	Publication date

UDIWG 2018-2	The architecture of the UDI database - Basic UDI-DI and UDI-DI attributes for medical devices and in-vitro diagnostic medical devices	March 2018
UDIWG 2018-1	UDI database. Definitions, descriptions and formats of the UDI core elements	March 2018

Current legislation

Guidance documents to assist stakeholders in implementing directives related to medical devices.

2. MEDDEVs Guidances

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. 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:

2.12 Market surveillance

MEDDEV 2.12/1 rev.8
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
Manufacturer Incident Report -
Version 7.2.1
MIR Field Safety Corrective
Action - FSCA
MIR and FSCA xml files (FSCA Report - Incident Report) Version 7.2.1

Other forms and templates
Field Safety

Notice Template Trend
Report
Periodic Summary Report

EU Vigilance Pilot on Trending – Additional MIR Form
EU Vigilance Pilot MIR form
EU Vigilance Pilot MIR Step-by-Step
Guide EU Vigilance Pilot Toolkit for
Users

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) - Guidance on the vigilance system for CE-marked medical devices
DSVG 04 - Breast Implants - Guidance on the vigilance system for CE-marked medical devices

	Title
2.1 Scope, field of application, definition	MEDDEV 2.1/1 Definitions of "medical devices", "accessory" and "manufacturer" **April 1994**
	MEDDEV 2.1/2 rev.2 Field of application of directive "active implantable medical devices" **April 1994**
	MEDDEV 2.1/2.1 Field of application of directive "active implantable medical devices" **February 1998**
	MEDDEV 2.1/3 rev.3 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 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
	MEDDEV 2.1/5 Medical devices with a measuring function **June 1998**

	MEDDEV 2.1/6 Qualification and Classification of stand alone software **July 2016**
2.2 Essential requirements	MEDDEV 2.2/1 rev.1 EMC requirements **February 1998**
	MEDDEV 2.2/3 rev.3 "Use by"-date **June 1998**
	MEDDEV 2.2/4 Conformity assessment of *In Vitro* Fertilisation (IVF) and Assisted Reproduction Technologies (ART) products **January 2012**

2.4 Classification MD	MEDDEV 2.4/1 rev.9 Classification of medical devices **June 2010**
2.5 Conformity assessment procedure	**General rules**
	Quality assurance. GHTF/SG4/N83:2010 - GHTF/SG4/N84:2010 Regulatory auditing of quality systems of medical device manufacturers (See document in the GHTF-Global Harmonization Task Force)
	MEDDEV 2.5/3 rev.2 Subcontracting quality systems related **June 1998**
	MEDDEV 2.5/5 rev.3 Translation procedure **February 1998**
	MEDDEV 2.5/6 rev.1 Homogenous batches (verification of manufacturers' products) **February 1998**
	Conformity assessment for particular groups of products
	MEDDEV 2.5/7 rev.1 Conformity assessment of breast implants **July 1998**
	MEDDEV 2.5/9 rev.1 Evaluation of medical devices incorporating products containing natural rubber latex **February 2004**
	MEDDEV 2.5/10 Guideline for Authorised Representatives **January 2012**

2.7 Clinical investigation, clinical evaluation	MEDDEV 2.7/1 rev.4 Clinical evaluation: Guide for manufacturers and notified bodies **June 2016** Appendix 1: Clinical evaluation on coronary stents **December 2008**
	MEDDEV 2.7/2 rev. 2 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 Clinical investigations: serious adverse reporting under directives 90/385/EEC and 93/42/EC - SAE reporting form **May 2015**
	The new SAE reporting form will be taken in use 1 September 2016 at the latest.
	MEDDEV 2.7/4 Guidelines on Clinical investigations: a guide for manufacturers and notified bodies **December 2010**
2.10 Notified bodies	MEDDEV 2.10/2 rev.1 Designation and monitoring of Notified Bodies within the framework of EC Directives on Medical devices Annex 1, Annex 2, Annex 3, Annex 4 **April 2001**

2.12 Market surveillance	MEDDEV 2.12/1 rev.8 Guidelines on a Medical Devices Vigilance System **January 2013** Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8 July 2019 **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 Manufacturer Incident Report - MIR Field Safety Corrective Action - FSCA MIR and FSCA xml files (FSCA Report - Incident Report) **Other forms and templates** Field Safety Notice Template) Trend Report Periodic Summary Report **EU Vigilance Pilot on Trending – Additional MIR Form** EU Vigilance Pilot MIR form EU Vigilance Pilot MIR Step-by-Step Guide EU Vigilance Pilot Toolkit for Users **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

	MEDDEV 2.12/2 rev.2 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
2.14 IVD	MEDDEV 2.14/1 rev.2 Borderline and Classification issues. A guide for manufacturers and notified bodies **January 2012**
	MEDDEV 2.14/2 rev.1 Research Use Only products **February 2004**
	MEDDEV 2.14/3 rev.1 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 DeviceDirective, Article 10 **January 2007**
	MEDDEV 2.14/4 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 Committees/Working Groups contributing to the implementation of the Medical Device Directives **December 2008**

Matrice Revisioni Certifico:

Rev.	Data	Oggetto	Autore
33.0	Settembre 2023	MDCG 2023-3 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices Febraury 2023 Q&A Rev. 1 Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the "sell off" periods July 2023 MDCG 2022-18 ADD.1 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate - Addendum 1 June 2023 MDCG 2020-16 Rev.2 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 Febraury 2023 MDCG 2020-3 Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD September 2023	Certifico Srl
32.0	Gennaio 2023	MDCG 2023-2 MDR form List of Standard Fees January 2023 MDCG 2023-2 IVDR form List of Standard Fees January 2023 MDCG 2023-2 List of Standard Fees January 2023 MDCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 January 2023 MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 December 2022 MDCG 2022-20 Substantial modification of performance study under Regulation (EU) 2017/746 December 2022 MDCG 2022-19 Performance study application/notification documents under Regulation (EU) 2017/746 December 2022 MDCG 2022-18 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate December 2022 MDCG 2022-17 MDCG position paper on "hybrid audits" December 2022 MDCG 2022-16 Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746 October 2022 MDCG 2022-15 Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD September 2022 MDCG 2022-14 Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs August 2022 MDCG 2022-4 rev.1 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD December 2022	Certifico Srl
31.0	Settembre 2022	MDCG 2022-13 Designation, re-assessment and notification of conformity assessment bodies and notified bodies MDCG 2022-12 Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)	Certifico Srl
30.0	Maggio 2022	MDCG 2022-11 MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements MDCG 2022-10 Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) MDCG 2022-9 Summary of safety and performance template MDCG 2022-8 Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC	Certifico Srl

		MDCG 2022-7 Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR	
29.0	Maggio 2022	MDCG 2022 - 5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical	Certifico Srl
28.0	Marzo 2022	MDCG 2022-4 - Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR MDCG 2022-3 - Verification of manufactured class D IVDs by notified bodies	Certifico Srl
27.0	Febbraio 2022	MDCG 2022-2 Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs) MDCG 2022-1 Notice to 3rd country manufacturers of SARS-CoV-2 in vitro diagnostic medical devices MDCG 2021-28 - Substantial modification of clinical investigation under Medical Device Regulation MDCG 2021-27 Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	Certifico Srl
26.0	Novembre 2021	MDCG 2021-26 - Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 MDCG 2021-25 - Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC MDCG 2019-6 v3 - Questions and answers: Requirements relating to notified bodies	Certifico Srl
25.0	Ottobre 2021	MDCG 2021-24 - Guidance on classification of medical devices Helsinki Procedure - Helsinki Procedure for borderline and classification under MDR & IVDR	Certifico Srl
24.0	Settembre 2021	MDCG 2021-6 Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation April 2021 MDCG 2021-7 Notice to manufacturers and authorised representatives on the impact of genetic variants on SARS-COV-2 in vitro diagnostic medical devices May 2021 MDCG 2021-08 Clinical investigation application/notification documents May 2021 MDCG 2021-09 MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers May 2021 MDCG 2021-10 - The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices May 2021 MDCG 2021-11 Guidance on Implant Card – Device types May 2021 MDCG 2021-12 FAQ on the European Medical Device Nomenclature (EMDN) June 2021 MDCG 2021-13 Rev. 1 Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR July 2021 MDCG 2021-14 Explanatory note on IVDR codes July 2021 MDCG 2021-15 Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR) July 2021 MDCG 2021-16 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) July 2021 MDCG 2021-17 Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR) July 2021 MDCG 2021-18 Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR) July 2021 MDCG 2021-19 Guidance note integration of the UDI within an organisation's quality management system July 2021	Certifico Srl

		MDCG 2021-20 Instructions for generating CIV-ID for MDR Clinical Investigations July 2021 MDCG 2021-21 Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices August 2021 MDCG 2021-22 Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746 August 2021 MDCG 2021-23 Guidance for notified bodies, distributors and importers onClarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746 August 2021	
23.0	Aprile 2021	MDCG 2021-5 Guidance on standardisation for medical devices MDCG 2021-4 Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746 MDCG 2021-3 Questions and Answers on Custom-Made	Certifico Srl
		Devices MDCG 2021-2 Guidance on state of the art of COVID-19 rapid antibody tests MDCG 2021-1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional MDCG 2020-18 MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers MDCG 2020-17 Questions and Answers related to MDCG 2020-4: "Guidance on temporary extraordinary measures related to medical device notified body audits during COVID- 19 quarantine orders and travel restrictions" MDCG 2020-16 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 MDCG 2020-15 MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States MDCG 2020-14 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR) MDCG 2020-13 Clinical evaluation assessment report template	
22.0	Luglio 2020	MDCG 2020-12 Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues Manufacturer Incident Report -Version 7.2.1 Manufacturer Incident Report -Version 7.2.1 import xml	Certifico Srl
21.0	Maggio 2020	MDCG 2020-11- Guidance on the renewal of designation and monitoring of notified bodies under Directives 90/385/EEC and 93/42/EEC to be performed in accordance with Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation MDCG 2020-10-2- Clinical Investigation Summary Safety Report Form v1.0 MDCG 2020-10-1- Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745	Certifico Srl
20.0	Aprile 2020	MDCG 2020-9	Certifico Srl
19.0	Aprile 2020	MDCG 2020-8 MDCG 2020-7 MDCG 2020-6 MDCG 2020-5	Certifico Srl

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17.0	Marzo 2020	MDCG 2020-3 MDCG 2020-2 MDCG 2020-1 MDCG 2019-8 v2 MDCG 2018-1 v3	Certifico Srl
16.0	Gennaio 2020	Guidance on Cybersecurity for medical devices	Certifico Srl
15.0	Dicembre 2019	Guidance notes for manufacturers of class I medical devices	Certifico Srl
14.0	Dicembre 2019	- Explanatory note on MDR codes - Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation	Certifico Srl
13.0	Novembre 2019	Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 Designating authority's final assessment form: Key information (EN)	Certifico Sr
12.0	Ottobre 2019	Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC	Certifico Srl
11.0	Settembre 2019	MDCG 2019-9 Summary of safety and clinical performance A guide for manufacturers and notified bodies DSVG 03 - Cardiac Implantable Electronic Devices (CIED) - Guidance on the vigilance system for CE-marked medical devices DSVG 04 - Breast Implants - Guidance on the vigilance system for CE-marked medical devices	Certifico Srl
10.0	Luglio 2019	MDCG Documents Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8	Certifico Srl
9.0	Aprile 2019	MDCG Documents	Certifico Srl
8.0	Marzo 2019	MDCG Documents	Certifico Srl
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6.0	Febbraio 2019	MDCG Documents	Certifico Srl
5.0	Gennaio 2019	MDCG Documents	Certifico Srl
4.0	Ottobre 2018	MDCG Documents	Certifico Srl
3.0	Agosto 2018	MDCG Documents	Certifico Srl
2.0	Agosto 2016	MEDDEV 2.1/6 MEDDEV 2.7/1 rev.4 DSVG Template DSVG 00 DSVG 01 DSVG 02	Certifico Srl
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