European Commission

Public Health

Guidance - MDCG endorsed documents and other guidance

This page provides a range of documents to assist stakeholders in applying Regulation (EU) 2017/745 on medical devices (MDR) EN ●●● and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices EN ●●●. The majority of documents on this page are endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR and Article 99 of the IVDR. They are drafted in collaboration with interested parties represented in the various groups and denominated by the following format: "MDCG Year-Number-revision".

The documents on this page are not legally binding. They present a common understanding of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation.

MDCG work in progress

Ongoing guidance documents EN ●●●

Borderline and Classification

Reference	Title	Publication
MDCG 2022-5 (/health/document/download/b5a27717-229f-4d7a-97b1-e1c7d819e579_en?filename=mdcg_2022-5_en_0.pdf) EN ●●●	Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices	April 2022

Reference	Title	Publication
MDCG 2021-24 EN ●●●	Guidance on **classification** of medical devices	October 2021
Helsinki Procedure EN ●●●	**Helsinki Procedure** for borderline and classification under MDR & IVDR	September 2021

Class I Devices

Reference	Title	Publication
MDCG 2020-2 rev.1 EN ●●●	**Class I transitional provisions** under Article 120 (3 and 4) – (MDR)	March 2020
MDCG 2019-15 rev.1 EN ●●●	Guidance notes for **manufacturers of class I** medical devices	December 2019

Clinical investigation and evaluation

Reference	Title	Publication
MDCG 2021-28 EN ●●●	**Substantial modification** of clinical investigation under Medical Device Regulation	December 2021
MDCG 2021-20 EN ●●●	Instructions for **generating CIV-ID** for MDR Clinical Investigations	July 2021
MDCG 2021-8 EN ●●●	Clinical investigation **application/notification documents**	May 2021
MDCG 2021-6 EN ●●●	Regulation (EU) 2017/745 – **Questions & Answers** regarding **clinical investigation**	April 2021
MDCG 2020-13 EN ●●● - Word version EN ●●●	**Clinical evaluation assessment report template**	July 2020

Reference	Title	Publication
MDCG 2020-10/2 EN ●●●	Guidance on **safety reporting** in clinical investigations	May 2020
MDCG 2020-10/1 EN ●●●	Appendix: Clinical investigation summary safety report form	May 2020
MDCG 2020-8 EN ●●●	Guidance on **PMCF evaluation report** template	April 2020
MDCG 2020-7 EN ●●●	Guidance on **PMCF plan** template	April 2020
MDCG 2020-6 EN ●●●	Guidance on sufficient **clinical evidence for legacy devices**	April 2020
MDCG 2020-5 EN ●●●	Guidance on **clinical evaluation – Equivalence**	April 2020
MDCG 2019-9 - Rev.1 EN ●●●	**Summary of safety and clinical performance**	March 2022

COVID-19

Reference	Title	Publication
MDCG 2022-1 (/health/document/download/cd617093-f2bd-4a99-9058-9805ce4d0db3_en?filename=mdcg_2022-1_en.pdf) EN ●●●	**Notice to 3rd country manufacturers** of SARS-CoV-2 in vitro diagnostic medical devices	January 2022
MDCG 2021-21 Rev.1 EN ●●●	Guidance on **performance evaluation of SARS-CoV-2** in vitro diagnostic medical devices	August 2021
MDCG 2021-7 EN ●●●	Notice to manufacturers and authorised representatives on the **impact of genetic variants on SARS-COV-2** in vitro diagnostic medical devices	May 2021
MDCG 2021-2 EN ●●●	Guidance on state of the art of **COVID-19 rapid antibody tests**	March 2021
COVID-19 TESTS: Q&A on in vitro diagnostic medical device conformity assessment and performance in the context of COVID-19 EN ●●● (available in all EU languages and Arabic (/health/document/download/1fec8a24-9e6d-4db0-9599-3dbe11a5ebaf_en?filename=covid-19_ivd-qa_ar.pdf) EN ●●●, Chinese (/health/document/download/8e99f052-ba7d-4489-a9a8-63aa379451c7_en?filename=covid-19_ivd-qa_zh.pdf) EN ●●●, Japanese EN ●●●, Russian EN ●●●)		February 2021
Conformity assessment procedures for protective equipment EN ●●●		July 2020

Reference	Title	Publication
How to verify that medical devices and personal protective equipment can be lawfully placed on the EU market and thus purchased and used – also in the COVID-19 context EN ●●●		May 2020
Guidance on regulatory requirements for medical face masks EN ●●●		June 2020
Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context EN ●●●		April 2020
Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19 EN ●●●		April 2020
MDCG 2020-9 EN ●●●	Regulatory requirements for **ventilators and related accessories**	April 2020

Custom-Made Devices

Reference	Title	Publication
MDCG 2021-3 EN ●●●	**Questions and Answers** on Custom-Made Devices	March 2021

EUDAMED

Reference	Title	Publication
MDCG 2021-13 Rev. 1 EN ●●●	**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 2021-1 Rev. 1 EN ●●●	Guidance on harmonised administrative practices and **alternative** technical **solutions until EUDAMED is fully functional**	May 2021
MDCG 2020-15 EN ●●●	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 2019-5 EN ●●●	**Registration of legacy devices** in EUDAMED	April 2019
MDCG 2019-4 EN ●●●	**Timelines for registration of device** data elements in EUDAMED	April 2019

European Medical Device Nomenclature (EMDN)

Reference	Title	Publication
MDCG 2021-12 EN ●●●	**FAQ** on the European Medical Device Nomenclature (**EMDN**)	June 2021
The EMDN – The nomenclature of use in EUDAMED EN ●●●		January 2020
The CND nomenclature – Background and general principles EN ●●●		January 2020
MDCG 2018-2 EN ●●●	Future EU medical device nomenclature - Description of requirements	March 2018

Implant cards

Reference	Title	Publication
MDCG 2021-11 EN ●●●	Guidance on **Implant Card – Device types**	May 2021
MDCG 2019-8 v2 EN ●●●	Guidance document **implant card** on the application of Article 18 Regulation (EU) 2017/745 on medical devices	March 2020

Importers & Distributors

Reference	Title	Publication
MDCG 2021-27 EN ●●●	Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	December 2021
MDCG 2021-26 EN ●●●	Q&A on **repackaging & relabelling** activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2021

In Vitro Diagnostic medical devices (IVD)

Reference	Title	Publication
MDCG 2022-9 (/health/document/download/b7cf356f-733f-4dce-9800-0933ff73622a_en?filename=mdcg_2022-9_en.pdf) EN ●●●	Summary of safety and performance template	May 2022

Reference	Title	Publication
MDCG 2022-8 (/health/document/download/76f9983e-164c-45f1-b2b9-c9e5050cefe9_en?filename=mdcg_2022-8_en.pdf) EN •••	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 2022-6 (/health/document/download/14c2d8dd-8489-4db5-b035-1c174f17fb54_en?filename=mdcg_2022-6.pdf) EN •••	Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR	May 2022
MDCG 2022-3 (/health/document/download/ebbc4f6a-4945-4d5d-9c22-9bc1aafc5532_en?filename=mdcg_2022-3_en.pdf) EN •••	Verification of manufactured class D IVDs by notified bodies	February 2022
MDCG 2022-2 (/health/document/download/f373538f-939c-472f-9536-436b6ddac085_en?filename=mdcg_2022-2_en.pdf) EN •••	Guidance on general principles of **clinical evidence** for In Vitro Diagnostic medical devices (IVDs)	January 2022
MDCG 2021-22 EN •••	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 2021-4 EN •••	Application of **transitional provisions** for certification of **class D** in vitro diagnostic medical devices according to Regulation (EU) 2017/746	April 2021

Reference	Title	Publication
MDCG 2020-16 Rev.1 EN ●●●	Guidance on **Classification Rules** for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	January 2022

New technologies

Reference	Title	Publication
Infographic EN ●●●	Is your **software** a Medical Device?	March 2021
MDCG 2020-1 EN ●●●	Guidance on **clinical evaluation** (MDR) / **Performance evaluation** (IVDR) of medical device software	March 2020
MDCG 2019-16 rev.1 EN ●●●	Guidance on **cybersecurity** for medical devices	December 2019
MDCG 2019-11 EN ●●●	**Qualification and classification of software** - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2019

Notified bodies

Reference	Title	Publication
MDCG 2022-4 (/health/document/download/e5714b2b-e98b-4fce-b5ff-d9141a8f30e1_en?filename=mdcg_2022-4_en.pdf) EN ●●●	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	February 2022
MDCG 2019-6 Rev.3 EN ●●●	Questions and answers: **Requirements relating to notified bodies**	October 2021

Reference	Title	Publication
MDCG 2021-23 EN ●●●	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 2021-18 EN ●●●	Applied-for scope of **designation and notification of a conformity assessment body** – Regulation (EU) 2017/746 (IVDR)	July 2021
MDCG 2021-17 EN ●●●	Applied-for scope of **designation and notification of a conformity assessment body** – Regulation (EU) 2017/745 (MDR)	July 2021
MDCG 2021-16 EN ●●●	**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 EN ●●●	**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

Reference	Title	Publication
MDCG 2021-14 EN ●●●	Explanatory note on **IVDR codes**	July 2021
MDCG 2020-17 EN ●●●	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 2020-14 EN ●●●	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 2020-12 EN ●●●	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

Reference	Title	Publication
MDCG 2020-11 EN ●●●	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 (EU) 920/2013	May 2020
MDCG 2020-4 EN ●●●	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 EN ●●●	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 2019-14 EN ●●●	Explanatory note on MDR codes	December 2019
MDCG 2019-13 EN ●●●	Guidance on sampling of devices for the assessment of the technical documentation	December 2019

Reference	Title	Publication
MDCG 2019-12 EN ●●●	Designating authority's final assessment form: Key information (EN)	October 2019
MDCG 2019-10 rev.1 EN ●●●	Application of transitional provisions concerning validity of certificates issued in accordance to the directives	October 2019
MDCG 2018-8 EN ●●●	Guidance on content of the certificates, voluntary certificate transfers	November 2018
NBOG BPG 2017-2 EN ●●●	Best practice guidance on the information required for personnel involved in conformity assessment	February 2018
NBOG BPG 2017-1 EN ●●●	Best practice guidance on designation and notification of conformity assessment bodies	February 2018
NBOG F 2017-8 EN ●●●	Review of qualification for the authorisation of personnel (IVDR)	February 2018
NBOG F 2017-7 EN ●●●	Review of qualification for the authorisation of personnel (MDR)	February 2018
NBOG F 2017-6 EN ●●●	Preliminary assessment review template (IVDR)	February 2018
NBOG F 2017-5 EN ●●●	Preliminary assessment review template (MDR)	February 2018

Standards

Reference	Title	Publication
MDCG 2021-5 EN ●●●	Guidance on **standardisation for medical devices**	April 2021

Unique Device Identifier (UDI)

Reference	Title	Publication
MDCG 2022-7 (/health/document/download/b5429d14-25a9-4cfc-b059-355388f03e05_en?filename=mdcg_2022-7_en.pdf) EN ●●●	Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)	May 2022
MDCG 2021-19 EN ●●●	Guidance note integration of the **UDI** within an organisation' s **quality management system**	July 2021
MDCG 2021-10 EN ●●●	The status of Appendixes **E-I of IMDRF N48** under the EU regulatory framework for medical devices	June 2021
MDCG 2021-09 EN ●●●	MDCG Position Paper on the Implementation of **UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers**	May 2021
MDCG 2018-1 Rev. 4 EN ●●●	Guidance on **basic UDI-DI and changes to UDI-DI**	April 2021
MDCG 2020-18 EN ●●●	MDCG Position Paper on **UDI assignment for Spectacle lenses & Ready readers**	December 2020

Reference	Title	Publication
MDCG 2019-2 EN ●●●	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 EN ●●●	MDCG guiding principles for **issuing entities rules on basic UDI-DI**	January 2019
MDCG 2018-7 EN ●●●	Provisional considerations regarding **language issues** associated with the **UDI database**	October 2018
MDCG 2018-6 EN ●●●	Clarifications of **UDI related responsibilities** in relation to **article 16**	October 2018
MDCG 2018-5 EN ●●●	**UDI assignment** to medical device **software**	October 2018
MDCG 2018-4 EN ●●●	Definitions/descriptions and formats of the **UDI core elements for systems or procedure packs**	October 2018
MDCG 2018-3 Rev.1 EN ●●●	Guidance on **UDI for systems and procedure packs**	June 2020

Other topics

Reference	Title	Publication
MDCG 2021-25 EN ●●●	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

Reference	Title	Publication
MDCG 2019-7 EN ●●●	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a '**person responsible for regulatory compliance**' (PRRC)	June 2019
MDCG 2019-3 rev.1 EN ●●●	**Clinical evaluation consultation procedure exemptions** Interpretation of article 54(2)b	April 2020

Other guidance documents

Reference	Title	Publication
European Medicines Agency (EMA) Guidance EN ●●●	Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746)	June 2021
SCHEER guidelines EN ●●●	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 (ED) properties	June 2019
CAMD FAQ EN ●●●	CAMD MDR/IVDR Transition Subgroup: FAQ – MDR Transitional provisions	January 2018

NEWS ANNOUNCEMENT | 20 MAY 2022

MDCG 2022-9 - Summary of safety and performance template

(/health/latest-updates/mdcg-2022-9-summary-safety-and-performance-template-2022-05-20_en)

NEWS ANNOUNCEMENT | 20 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

(/health/latest-updates/mdcg-2022-8-regulation-eu-2017746-application-ivdr-requirements-legacy-devices-and-devices-placed-2022-05-20_en)

NEWS ANNOUNCEMENT | 20 MAY 2022

MDCG 2022-7 - Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746

(/health/latest-updates/mdcg-2022-7-qa-unique-device-identification-system-under-regulation-eu-2017745-and-regulation-eu-2022-05-20_en)

NEWS ANNOUNCEMENT | 4 MAY 2022

MDCG 2022-6 - Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR

(/health/latest-updates/mdcg-2022-6-guidance-significant-changes-regarding-transitional-provision-under-article-1103-ivdr-2022-05-04_en)

See all *(https://ec.europa.eu/health/medical-devices-sector/latest-updates_en)*

Events

(https://ec.europa.eu/health/medical-devices-sector/events_en?f%5B0%5D=topic_topic%3A143)

Publications

(https://ec.europa.eu/health/medical-devices-sector/publications_en?f%5B0%5D=oe_publication_type%3Ahttp%3A//publications.europa.eu/resource/authority/resource-type/PUB_GEN)