| **Reference** | **Title** | **Publication** |
| --- | --- | --- |
| [MDCG 2020-18](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_18_en.pdf%22%20%5Ct%20%22_blank) | MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers | December 2020 |
| [MDCG 2019-2](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_2_gui_udi_dev_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_1_budi_rules_ie_en.pdf%22%20%5Ct%20%22_blank) | MDCG guiding principles for issuing entities rules on basic UDI-DI | January 2019 |
| [MDCG 2018-7](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018_7_languages_en.pdf%22%20%5Ct%20%22_blank) | Provisional considerations regarding language issues associated with the UDI database | October 2018 |
| [MDCG 2018-6](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018_6_art16_en.pdf%22%20%5Ct%20%22_blank) | Clarifications of UDI related responsibilities in relation to article 16 | October 2018 |
| [MDCG 2018-5](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018_5_software_en.pdf%22%20%5Ct%20%22_blank) | UDI assignment to medical device software | October 2018 |
| [MDCG 2018-4](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018_4_udi_core_spp_en.pdf%22%20%5Ct%20%22_blank) | Definitions/descriptions and formats of the UDI core elements for systems or procedure packs | October 2018 |
| [MDCG 2018-3 Rev.1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2018-3-guidance-udi-spp_en.pdf%22%20%5Ct%20%22_blank) | Guidance on UDI for systems and procedure packs | June 2020 |
| [MDCG 2018-2](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018_2_nomenclature_en.pdf%22%20%5Ct%20%22_blank) | Future EU medical device nomenclature - Description of requirements | March 2018 |
| [MDCG 2018-1 v3](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018-1_guidance_udi-di_en.pdf%22%20%5Ct%20%22_blank) | Guidance on basic UDI-DI and changes to UDI-DI | March 2020 |

**EUDAMED**

| **Reference** | **Title** | **Publication** |
| --- | --- | --- |
| [MDCG 2020-15](https://ec.europa.eu/health/sites/health/files/md_sector/docs/2020-15-position-paper-actor-registration-module_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_5_legacy_devices_registration_eudamed_en.pdf%22%20%5Ct%20%22_blank) | Registration of legacy devices in EUDAMED | April 2019 |
| [MDCG 2019-4](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_4_devices_registration_eudamed_en.pdf%22%20%5Ct%20%22_blank) | Timelines for registration of device data elements in EUDAMED | April 2019 |

**European Medical Device Nomenclature (EMDN)**

| **Title** | **Publication** |
| --- | --- |
| [The EMDN – The nomenclature of use in EUDAMED](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_emdn_eudamed_nomenclature_en.pdf%22%20%5Ct%20%22_blank) | January 2020 |
| [The CND nomenclature – Background and general principles](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_cnd_general_principles_en.pdf%22%20%5Ct%20%22_blank) | January 2020 |

**Notified bodies**

| **Reference** | **Title** | **Publication** |
| --- | --- | --- |
| [MDCG 2020-17](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-17-guidance-mdcg-qa_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-14-guidance-mdsap_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-12_guidance_transitional_provisions_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-11_guidance_renewal_designation_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_4_nb_audits_covid-19_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_guidance_significant_changes_annexes_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_14_mdr_codes_en.pdf%22%20%5Ct%20%22_blank) | Explanatory note on MDR codes | December 2019 |
| [MDCG 2019-13](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_13_sampling_mdr_ivdr_en.pdf%22%20%5Ct%20%22_blank) | Guidance on sampling of devices for the assessment of the technical documentation | December 2019 |
| [MDCG 2019-12](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_key_information_form_en.docx) | Designating authority's final assessment form: Key information (EN) | October 2019 |
| [MDCG 2019-10 rev.1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_application-transitional-provisions-certificates_en.pdf%22%20%5Ct%20%22_blank) | Application of transitional provisions concerning validity of certificates issued in accordance to the directives | October 2019 |
| [MDCG 2019-6 v2](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_qa_requirements_notified_bodies_en.pdf%22%20%5Ct%20%22_blank) | Questions and answers: Requirements relating to notified bodies | October2019 |
| [MDCG 2018-8](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018_8_crf_transfer_en.pdf%22%20%5Ct%20%22_blank) | Guidance on content of the certificates, voluntary certificate transfers | November 2018 |
| [NBOG BPG 2017-2](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_2_nbog_bpg_en.pdf%22%20%5Ct%20%22_blank) | Best practice guidance on the information required for personnel involved in conformity assessment | February 2018 |
| [NBOG BPG 2017-1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_1_nbog_bpg_en.pdf%22%20%5Ct%20%22_blank) | Best practice guidance on designation and notification of conformity assessment bodies | February 2018 |
| [NBOG F 2017-8](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_8_nbog_mdr_en.doc) | Review of qualification for the authorisation of personnel (IVDR) | February 2018 |
| [NBOG F 2017-7](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_7_nbog_mdr_en.doc) | Review of qualification for the authorisation of personnel (MDR) | February 2018 |
| [NBOG F 2017-6](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_6_nbog_mdr_en.docx) | Preliminary assessment review template (IVDR) | February 2018 |
| [NBOG F 2017-5](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_5_nbog_mdr_en.docx) | Preliminary assessment review template (MDR) | February 2018 |
| [NBOG F 2017-4](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_4_nbog_mdr_en.docx) | Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR) | February 2018 |
| [NBOG F 2017-3](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_3_nbog_mdr_en.docx) | Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR) | February 2018 |
| [NBOG F 2017-2](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_2_nbog_mdr_en.docx) | Application form to be submitted by a conformity assessment body when applying for designation as a notified body under the in vitro diagnostic devices regulation (IVDR) | February 2018 |
| [NBOG F 2017-1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2017_1_nbog_mdr_en.docx) | Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR) | February 2018 |

**Clinical investigation and evaluation**

| **Reference** | **Title** | **Publication** |
| --- | --- | --- |
| [MDCG 2020-13](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-13-cea-report-template_en.pdf%22%20%5Ct%20%22_blank) - [Word version](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-13-cea-report-template_en.docx%22%20%5Ct%20%22_blank) | Clinical evaluation assessment report template | July 2020 |
| [MDCG 2020-10/2](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-10-2_guidance_safety_report_form_en.xlsx)[MDCG 2020-10/1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-10-1_guidance_safety_reporting_en.pdf%22%20%5Ct%20%22_blank) | Guidance on safety reporting in clinical investigationsAppendix: Clinical investigation summary safety report form | May 2020May 2020 |
| [MDCG 2020-8](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_8_guidance_pmcf_evaluation_report_en.pdf%22%20%5Ct%20%22_blank) | Guidance on PMCF evaluation report template | April 2020 |
| [MDCG 2020-7](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_7_guidance_pmcf_plan_template_en.pdf%22%20%5Ct%20%22_blank) | Guidance on PMCF plan template | April 2020 |
| [MDCG 2020-6](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_6_guidance_sufficient_clinical_evidence_en.pdf%22%20%5Ct%20%22_blank) | Guidance on sufficient clinical evidence for legacy devices | April 2020 |
| [MDCG 2020-5](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_5_guidance_clinical_evaluation_equivalence_en.pdf%22%20%5Ct%20%22_blank) | Guidance on clinical evaluation – Equivalence | April 2020 |
| [MDCG 2019-9](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_9_sscp_en.pdf%22%20%5Ct%20%22_blank) | Summary of safety and clinical performance | August 2019 |

**New technologies**

| **Reference** | **Title** | **Publication** |
| --- | --- | --- |
| [MDCG 2020-1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_1_guidance_clinic_eva_md_software_en.pdf%22%20%5Ct%20%22_blank) | Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software | March 2020 |
| [MDCG 2019-16 rev.1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_cybersecurity_en.pdf%22%20%5Ct%20%22_blank) | Guidance on cybersecurity for medical devices | December 2019 |
| [MDCG 2019-11](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_11_guidance_qualification_classification_software_en.pdf%22%20%5Ct%20%22_blank) | Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 | October 2019 |

**Other topics**

| **Reference** | **Title** | **Publication** |
| --- | --- | --- |
| [MDCG 2020-16](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_guidance_classification_ivd-md_en.pdf%22%20%5Ct%20%22_blank) | Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 | November 2020 |
| [MDCG 2020-9](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-9_regulatory_requirements_ventilators_en.pdf%22%20%5Ct%20%22_blank) | Regulatory requirements for ventilators and related accessories | April 2020 |
| [MDCG 2020-2 rev.1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_transitional-provisions-art-3-and-4_en.pdf%22%20%5Ct%20%22_blank) | Class I transitional provisions under Article 120 (3 and 4) – (MDR) | March 2020 |
| [MDCG 2019-15 rev.1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_guidance-manufacturers_en.pdf%22%20%5Ct%20%22_blank) | Guidance notes for manufacturers of class I medical devices | December 2019 |
| [MDCG 2019-8 v2](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_8_implant_guidance_card_en.pdf%22%20%5Ct%20%22_blank) | Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices | March 2020 |
| [MDCG 2019-7](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_7_guidance_art15_mdr_ivdr_en.pdf%22%20%5Ct%20%22_blank) | 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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_3_rev1_cecp_en.pdf%22%20%5Ct%20%22_blank) | Interpretation of article 54(2)b | April 2020 |

**Commission guidance documents**

| **Title** | **Publication** |
| --- | --- |
| [Conformity assessment procedures for protective equipment](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_qa_conformity_assessment_en.pdf%22%20%5Ct%20%22_blank) | July 2020 |
| [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](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_qa_conformity_documents_en.pdf%22%20%5Ct%20%22_blank) | May 2020 |
| [Guidance on regulatory requirements for medical face masks](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_guidance-reg-req-med-face-masks.pdf%22%20%5Ct%20%22_blank) | June 2020 |
| [Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_guidance_md_qa_covid-19_en.pdf%22%20%5Ct%20%22_blank) | April 2020 |
| [Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_qa_3d_ppp_covid-19_en.pdf%22%20%5Ct%20%22_blank) | April 2020 |

**Other guidance documents**

| **Reference** | **Title** | **Publication** |
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| [SCHEER guidelines](https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_015.pdf%22%20%5Ct%20%22_blank) | Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devicescovering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties | June 2019 |
| [CAMD FAQ](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_camd_mdr_en.pdf%22%20%5Ct%20%22_blank) | CAMD MDR/IVDR Transition Subgroup: FAQ – MDR Transitional provisions | January 2018 |