

## Overview over guidance documents and recommendations

This document serves as an update to the one provided with the “Starterkit I”. It contains a short description and links to the freely available information on medical devices, the directives and the new Medical Devices Regulation without claiming completeness but with the intention to present an overview of the currently available guidance documents.

The DQS Medizinprodukte GmbH is neither responsible for the content of the linked pages, nor for the content and correctness of the information and documents presented on these pages.

## Übersicht über Leitfäden und Empfehlungen

Dieses Dokument dient als Aktualisierung des im „Starterkit I“ enthaltenen Übersicht über regulatorische Information im Netz. Es enthält eine kurze Beschreibung und Links zu den frei verfügbaren Informationen über Medizinprodukte, die Richtlinien und die neue Medizinprodukteverordnung, ohne Anspruch auf Vollständigkeit, jedoch mit der Absicht einen Überblick über die derzeit verfügbaren Leitfäden zu geben.

Die DQS Medizinprodukte GmbH ist weder für den Inhalt der verlinkten Seiten, noch für den Inhalt und die Richtigkeit der auf diesen Seiten dargestellten Informationen und Dokumente verantwortlich.

### New Regulations on medical devices

Factsheets with basic information for all stakeholders

Link: [Factsheets](#)

### Blue Guide

The Blue Guide is a publication by the European Commission that offers CE Marking information and advice on the implementation of EU product directives and regulations. It describes how products are made available and placed on the European market. This guidance document has been revised in 2016 to reflect the current legislative framework, including the **Active Implantable Medical Devices Directive 90/385/EEC**, the **Medical Devices Directive 93/42/EEC** and the **In Vitro Diagnostic Medical Devices Directive 98/79/EC**

Link: [Blue Guide](#)

### Regulation (EU) 2017/745

#### Second Corrigendum to Regulation (EU) 2017/745

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 and

Corrigendum to 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 (OJ L 117, 5.5.2017)

Link: [Regulation \(EU\) 2017/745](#)  
[Second Corrigendum to Regulation \(EU\) 2017/745](#)

### Harmonized Standards

Harmonized Standards are published in the Official Journal of the European Union. These standards are European Standards (EN) produced under a mandate (“standardization request”) from the European Commission and transposed into national standards by Member States of the EU. Harmonized Standards implement **essential requirements** adopted by National Standards Organizations. Compliance with harmonized standards provides a **presumption of conformity** with the corresponding requirements of harmonization legislation.

Link: [Commission Implementing Decision \(EU\) 2020/437 of 24 March 2020 on the harmonized standards for medical devices](#)

### MEDDEV (Medical Devices)

These guidance documents aim to assist stakeholders in implementing the **medical device directives**. 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. 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.

Link: [MEDDEV documents - guidance for implementing the medical directives](#)

#### **NBOG best practice guides**

The Notified Body Operations Group (NBOG) was founded in July 2000 by an agreement of Member States and the European Commission.

This group is tasked to improve the overall performance of Notified Bodies in the medical devices sector by identifying and writing best practice documents to be adopted by both Notified Bodies and those organizations responsible for their designation and control (e.g. DAkkS and ZLG in Germany).

Link: [NBOG best practice guides - directive related guidance documents](#)

#### **NBOG (The European Association for Medical Devices of Notified Bodies)**

This association has been founded 2001 with the means for protecting the interests of Notified Bodies. The association is involved on the implementation of the MDR and the IVDR, e.g. by supporting Notified Bodies by creating and updating of guidance documents and writing position papers

Link: [Team NB documents](#)

#### **NB-MED (European Exchange of Experience of Notified Bodies in the Field of Medical Devices)**

The NB-MED consists of representatives of manufacturer associations, member of the European Commission and of course representatives of the Notified Bodies. The NB-MED creates and approves NB-MED recommendations that are edited in the framework of the NB-Med working group.

Link: [NB-MED Recommendations](#)

#### **(IMDRF) International Medical Device Regulators Forum**

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.

It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

Link: [IMDRF-Guidance documents](#)

#### **MDCG (medical devices coordination group)**

The European Commission provides a range of guidance documents to assist stakeholders in implementing the **medical devices regulations**.

These documents originate from various sources and are legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) in accordance with **Article 105 of Regulation 745/2017**, pursue the objective of ensuring uniform application of the relevant provisions of the regulations within the EU.

Note that all guidance and implementing measures under the current Directives will be reviewed over the next few years in the light of the texts of the 2 new regulations and only documents endorsed by the MDCG may be used as guidance for implementing the **Regulation (EU) 745/2017**.

Please find below a list of all MDCG documents published until the end of March.

Link: [MDCG endorsed documents - guidance for implementing the MDR](#)

Title	Publication	Date
UDI (Unique Device Identification)		
<a href="#">MDCG 2019-1</a>	MDCG guiding principles for issuing entities rules on basic UDI-DI	01/ 2019

Title	Publication	Date
<a href="#">MDCG 2019-2</a>	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	02/ 2019
<a href="#">MDCG 2018-1 v3</a>	Guidance on Basic UDI-DI and changes to UDI-DI	03/ 2020
<a href="#">MDCG 2018-2</a>	Future EU medical device nomenclature - Description of requirements	03/ 2018
<a href="#">MDCG 2018-3 v1</a>	Guidance on UDI for systems and procedure packs	10/ 2018
<a href="#">MDCG 2018-4</a>	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs	10/ 2018
<a href="#">MDCG 2018-5</a>	UDI assignment to medical device software	10/ 2018
<a href="#">MDCG 2018-6</a>	Clarifications of UDI related responsibilities in relation to article 16	10/ 2018
<a href="#">MDCG 2018-7</a>	Provisional considerations regarding language issues associated with the UDI database	10/ 2018

#### EUDAMED (European Databank on Medical Devices)

Title	Publication	Date
<a href="#">MDCG 2019-4</a>	Timelines for registration of device data elements in EUDAMED	04/ 2019
<a href="#">MDCG 2019-5</a>	Registration of legacy devices in EUDAMED	04/ 2019

#### EMDN (European Medical Device Nomenclature)

Title	Publication	Date
	<a href="#">The European Medical Device Nomenclature (EMDN) - the nomenclature of use in EUDAMED</a>	01/ 2020
	<a href="#">The CND nomenclature - background an general principles</a>	01/ 2020

#### NB (Notified Bodies)

Title	Publication	Date
<a href="#">MDCG 2020-12</a>	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 tissue	06/ 2020
<a href="#">MDCG 2020-11</a>	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	05/ 2020
<a href="#">MDCG 2020-4</a>	Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions	04/ 2020
<a href="#">MDCG 2020-3</a>	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	03/ 2020
<a href="#">MDCG 2019-14</a>	Explanatory note on MDR codes	12/ 2019
<a href="#">MDCG 2019-13</a>	Guidance on sampling of devices for the assessment of the technical documentation	12/ 2019
<a href="#">MDCG 2019-12</a>	Designating authority's final assessment form: Key information (EN)	10/ 2019
<a href="#">MDCG 2019-10</a>	Application of transitional provisions concerning validity of certificates issued in accordance to the directives	10/ 2019

<b>Title</b>	<b>Publication</b>	<b>Date</b>
<a href="#">MDCG 2019-6 v2</a>	Questions and answers: Requirements relating to notified bodies	10/ 2019
<a href="#">MDCG 2018-8</a>	Guidance on content of the certificates, voluntary certificate transfers	11/ 2018
<a href="#">NBOG BPG 2017-1</a>	Best practice guidance on designation and notification of conformity assessment bodies	02/ 2018
<a href="#">NBOG BPG 2017-2</a>	Best practice guidance on the information required for personnel involved in conformity assessment	02/ 2018
<a href="#">NBOG F 2017-1</a>	Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR)	02/ 2018
<a href="#">NBOG F 2017-2</a>	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)	02/ 2018
<a href="#">NBOG F 2017-3</a>	Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR)	02/ 2018
<a href="#">NBOG F 2017-4</a>	Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR)	02/ 2018
<a href="#">NBOG F 2017-5</a>	Preliminary assessment review template (MDR)	02/ 2018
<a href="#">NBOG F 2017-6</a>	Preliminary assessment review template (IVDR)	02/ 2018
<a href="#">NBOG F 2017-7</a>	Review of qualification for the authorisation of personnel (MDR)	02/ 2018
<a href="#">NBOG F 2017-8</a>	Review of qualification for the authorisation of personnel (IVDR)	02/ 2018

### Clinical investigation and evaluation

<b>Title</b>	<b>Publication</b>	<b>Date</b>
<a href="#">MDCG 2020-13</a>	Clinical evaluation assessment report template	07/ 2020
<a href="#">MDCG 2020-10/1</a>	Guidance on safety reporting in clinical investigations	05/ 2020
<a href="#">MDCG 2020-10/2</a>	Appendix: Clinical investigation summary safety report form	
<a href="#">MDCG 2020-8</a>	Guidance on PMCF evaluation report template	04/2020
<a href="#">MDCG 2020-7</a>	Guidance on PMCF plan template	04/2020
<a href="#">MDCG 2020-6</a>	Guidance on sufficient clinical evidence for legacy devices	04/2020
<a href="#">MDCG 2020-5</a>	Guidance on clinical evaluation – Equivalence	04/2020
<a href="#">MDCG 2019-9</a>	Summary of safety and clinical performance	08/2019

### New technologies

<b>Title</b>	<b>Publication</b>	<b>Date</b>
<a href="#">MDCG 2020-1</a>	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software	03/2020
<a href="#">MDCG 2019-11</a>	Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	10/2019
<a href="#">MDCG 2019-16 v1</a>	Guidance on cybersecurity for medical devices	12/2019

### Other Topics

Title	Publication	Date
<b>Title</b>	<b>Publication</b>	<b>Date</b>
<a href="#">MDCG 2020-9</a>	Regulatory requirements for ventilators and related accessories	04/2020
<a href="#">MDCG 2020-2</a>	Class I Transitional provisions under Article 120 (3 and 4) – (MDR)	03/ 2020
<a href="#">MDCG 2019-8 v2</a>	Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices	03/ 2020
<a href="#">MDCG 2019-15 v1</a>	Guidance notes for manufacturers of class I medical devices	12/ 2019
<a href="#">MDCG 2019-7</a>	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)	06/ 2019
<a href="#">MDCG 2019-3</a>	Interpretation of article 54(2)b	03/ 2019

#### Other MDCG Documents

Title	Publication	Date
<a href="#">UDIWG 2018-1</a>	UDI database. Definitions, descriptions and formats of the UDI core elements	03/ 2018
<a href="#">UDIWG 2018-2</a>	The architecture of the UDI database - Basic UDI-DI and UDI-DI attributes for medical devices and in vitro diagnostic medical devices	03/ 2018

#### Commission guidance documents

Title	Publication	Date
	<a href="#">Conformity assessment procedures for protective equipment</a>	07/2020
	<a href="#">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</a>	05/2020
	<a href="#">Guidance on regulatory requirements for medical face masks</a>	06/2020
	<a href="#">Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context</a>	04/2020
	<a href="#">Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19</a>	04/2020

#### Other Guidance Documents

<a href="#">SCHEER guidelines</a>	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	06/ 2019
<a href="#">CAMD FAQ</a>	CAMD MDR/IVDR Transition Subgroup: FAQ – MDR Transitional provisions	01/2018