



## Main product contacts - Applicable Standards-Laws-Guidelines

### Product group designation

### Surgical Instruments

DIN	Designation	Date of issue
DIN 96298-3	Medical instruments - Definitions, measurement methods and testing - Part 3: Testing	01.10.2017
DIN 100 Part 1	Medical instruments 1 - Basic standards, cutting instruments, ENT instruments, hammers and reprocessing	01.06.2018
DIN 100 Part 2	Medical instruments 2 - Non-cutting instruments	01.06.2018
DIN 50103-3 - 2017	Testing of metallic materials - Rockwell hardness test - Part 3: Modified Rockwell methods Bm and Fm for steel sheet (Foreign Standard)	01.01.2017
DIN 58298	Materials; design and testing of medical instruments	01.09.2010
DIN 58299-2014	Serrations (grooves) for surgical instruments - Profile angles, pitches	19.07.2021
DIN 58300-2014	Closure types for surgical instruments	01.02.2014
DIN 96298-1	Medical instruments - Definitions, measurement methods and testing - Part 1: Definitions	01.10.2016
DIN 96298-2	Medical instruments - Definitions, measuring methods and testing - Part 2: Measuring methods for determining the basic dimensions of standard surgical instruments	01.10.2016

DIN / ISO	Designation	Date of issue
DIN ISO 2859-1	++ Acceptance sampling based on the number nonconforming units or defects (attribute inspection) - Part 1: Sampling schemes organised by acceptable quality limit (AQL) for the inspection of a series of lots - (ISO 2859-1:1999 Cor. 1:2001 Amd.1:2011)	01.08.2014

DIN / EN / ISO	Designation	Date of issue
DIN EN ISO 10151	Stainless steel strip for springs - Technical delivery conditions; German version EN 10151:2002	01.02.2003
DIN EN ISO 10993-23_2021-10	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021); German version EN ISO 10993-23:2021	01.10.2021
DIN EN ISO 11737-2	Sterilisation of health care products - Microbiological methods - Part 2: Tests for sterility in the definition, validation and maintenance of a sterilisation process (ISO 11737-2:2019); German version EN ISO 11737-2:2020	01.07.2020
DIN EN ISO 286-1_2019-09	+Geometrical product specification (GPS) - ISO tolerance system for linear dimensions - Part 1: Principles for tolerances, allowances and fits (ISO 286-1:2010 Cor 1:2013); German version EN ISO 286-1:2010 + AC:2013	01.09.2019
DIN EN ISO 20417_2024_02	Medical devices - Requirements for information to be provided by the manufacturer (ISO/DIS20417:2024); Draft	01.02.2024
DIN EN ISO 17665_2024	Sterilisation of healthcare products - Moist heat - Part 1: Requirements for the development, validation and control of the use of a sterilisation process for medical devices (ISO 17665-1:2024-09); German version EN ISO 17665-1:2024	01.09.2024
DIN EN ISO 14971 2022 04	Medical devices _ Application of risk management to medical devices (EN ISO 14971:2019-)	01.04.2022
DIN EN ISO 14155_2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020); German version EN ISO 14155:2020	30.04.2021



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DIN EN ISO 13485_2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016); German version EN ISO 13485:2016	19.11.2021
DIN EN ISO 13402_2001_02	Surgical and dental hand instruments: Determination of resistance to sterilisation, corrosion and heat treatment (ISO 13402:1995) German version EN ISO 13402:2000  Surgical and dental hand instruments Determination of resistance against autoclaving, corrosion and thermal exposure	01.02.2001
DIN EN ISO 5832_3_2022	Surgical implants - Metallic materials - Part 3: Titanium 6-aluminium 4-vanadium wrought alloy (ISO 5832-3:2021); German version EN ISO 5832-3:2021	21.01.2022
DIN EN ISO 11137-1	Sterilisation of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021); German version EN ISO 11737-1:2018 + A1:2021	01.04.2020
DIN EN ISO 10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016); German version EN ISO 10993-6:2016	01.09.2017
DIN EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009); German version EN ISO 10993-5:2009	01.10.2009
DIN EN ISO 5832-1	Surgical implants - Metallic materials - Part 1: Stainless steel (ISO 5832-1:2016); German version EN ISO 5832-1:2019	01.07.2024
DIN EN ISO 10993-3	Biological assessment of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014); German version EN ISO 10993-3:2014	01.02.2015
DIN EN ISO 20417_2022-03	Medical devices Requirements for information to be provided by the manufacturer	23.02.2022
DIN EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterisation of materials for medical devices as part of a risk management system (ISO 10993-18:2023); German version EN ISO 10993-18:2020 + A1:2023	01.11.2023
DIN EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012); German version EN ISO 10993-12:2012	01.08.2021
DIN EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Systemic toxicity (ISO 10993-11:2017); German version EN ISO 10993-11:2018	01.09.2018
DIN EN ISO 10993-10_2023	Biological assessment of medical devices - Part 10: Tests for irritation and skin sensitisation (ISO 10993-10:2021); German version EN ISO 10993-10:2023	01.04.2023
DIN EN ISO 10993-1_2021	Biological evaluation of medical devices - Part 1: Assessments and tests within a risk management system	01.05.2021
DIN EN ISO 10993-4	DIN EN ISO 10993-4:2017-12 Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood (ISO 10993-4:2017); German version EN ISO 10993-4:2017	01.12.2017
DIN EN ISO 6931-1	Stainless steels for springs - Part 1: Wire (ISO 6931-1:2016); German version EN ISO 6931-1:2020	01.11.2020



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DIN EN ISO 7153-1\_2\_2017 Surgical instruments - Materials - Part 1: Metals (ISO 7153-1:2016); German version EN ISO 7153-1:2016 01.02.2017

DIN EN ISO 15223\_1\_2022 Medical device symbols for use as part of the information to be provided by the manufacturer Part 1: General requirements (ISO 15223-1:2021); German version EN ISO 15223-1:2021 21.01.2022

EN / ISO	Designation	Date of issue
EN ISO 17664-1_2021	Reprocessing of healthcare products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021); German version EN ISO 17664-1:2021	02.11.2021

Regulations	Designation	Date of issue
2013_172_EU_Commission_Recommendation	Commission Recommendation of 5 April 2013 on a common framework for a system of unique product identifiers for medical devices in the Union	05.04.2013
MPAMIV - Ordinance on the Reporting of Suspected Serious Incidents involving Medical Devices	Ordinance on the Reporting of Suspected Serious Incidents involving Medical Devices and on the Exchange of Information between the Competent Authorities (Medical Device User Notification and Information Ordinance - MPAMIV)	21.04.2021
2017_745_EU_MDR_Verordnung	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	05.04.2017
2017_745_EU_Corrigendum_Rev2_20191227_dt	EUV 2017/745 Ber 2019, Issue: 27: December 2019 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.	27.12.2019

DIN / EN	Designation	Date of issue
DIN EN 10088-2	Stainless steels - Part 2: Technical delivery conditions for sheet and strip of corrosion resisting steels for general purposes  Stainless steels - Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes	01.01.2025
DIN EN 62366-1 (VDE 0750-241-1)_2021-08	Medical devices - Part 1: Application of fitness for use to medical devices (IEC 62366-1:2015 + COR1:2016); German version EN 62366-1:2015 +AC:2015	09.08.2021
DIN EN 1484	Water analysis - Guidance for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC); German version EN 1484:1997	01.04.2019
DIN EN 10088-3	Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire rod, drawn wire, sections and bright products of corrosion resisting steels for general purposes  Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes;	01.04.2024
DIN EN 10088_1_2024_04	Stainless Steels-Part 1: List of Stainless Steels Stainless Steels-Part 1: List of Stainless Steels	01.04.2024



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DIN EN 10204	Metallic products - Types of inspection certificates; German version EN 10204:2004	01.01.2005
<b>Draft DIN / EN</b>	<b>Designation</b>	<b>Date of issue</b>
DIN EN 10088-2_2022-01_draft	Stainless steels - Part 2: Technical delivery conditions for sheet and strip of corrosion resisting steels for general purposes; German and English version prEN 10088-2:2021	01.01.2022
<b>Draft DIN / EN / ISO</b>	<b>Designation</b>	<b>Date of issue</b>
ISO_FDIS_15883-1 Draft	Washer-disinfectors- Part 1: General requirements, terms and definitions and test	01.01.2021
DIN EN ISO 15223-1 Draft	ISO 15223-1 DAM 1 DraftMedical devices Symbols to be used on medical device labels; Labelling and information to be provided_Part 1_General requirements	01.06.2024
DIN EN ISO 13402_2024-01_draft	DIN EN ISO 13402_2024-01_draft Surgical and dental hand instruments - Determination of resistance to sterilisation, corrosion and heat treatment (ISO/DIS 13402:2023); German and English version prEN ISO 13402:2023	09.01.2024
<b>Standards</b>	<b>Designation</b>	<b>Date of issue</b>
MPBetreibV	Ordinance on the Installation, Operation and Use of Medical Devices (Medical Devices Operator Ordinance - MPBetreibV)	21.04.2021
<b>ASTM</b>	<b>Designation</b>	<b>Date of issue</b>
ASTM A967_A 967M_2017	Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts	01.01.2017
ASTM A380	Standard Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems	01.05.2018
ASTM_F899-23	Standard Specification for Wrought Stainless Steels for Surgical Instruments	01.11.2023
<b>MEDDEV</b>	<b>Designation</b>	<b>Date of issue</b>
MEDDEV 2.12_1_rev8	Guidelines on a Medical Device Vigilance System	01.01.2013
MEDDEV 2.7_1_rev4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC	01.06.2016
MEDDEV 2.12_2_rev2	Post Market Clinical Follow-up Studies - A Guide for Manufacturers and Notified Bodies	01.01.2012
<b>Guidelines</b>	<b>Designation</b>	<b>Date of issue</b>
NB-MED_2.5.1_Rec.5	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC Technical Documentation; 2.5.1 Conformity assessment procedures; General rules [Rev.-No. 4, accepted 29.02.2000]	29.02.2000
MPDG	Act on the Implementation of Union Regulations on Medical Devices (Medical Devices Implementation Act - MPDG)	28.04.2020



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MPAMIV	Regulation on the reporting of suspected serious incidents involving medical devices and the exchange of information between competent authorities (Medical Devices User Notification and Information Ordinance - MPAMIV)	21.04.2021
Guidlines of phthalates (plasticisers)	Guidlines of phthalates (plasticisers)	18.06.2019
21_CFR_Part_820_Vol8	FDA - CFR Code of Federal Regulations, Title 21 Part 820 Quality System Regulations [Revised as of April 1, 2018]	01.04.2018
1907_2006_EG_REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18.12.2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) + Corrigendum of 29.05.2007	29.05.2007
<b>MDCG</b>	<b>Designation</b>	<b>Date of issue</b>
MDCG_2020_6_guidance_sufficient_clinical_evidence_en_0	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	01.04.2020
MDCG_2022-4_Article_120_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	05.02.2022
MDCG_2021-28_Substantial modification of clinical investigation under Medical Device Regulation_en	Substantial modification of clinical investigation under Medical Device Regulation	01.12.2021
MDCG_2020-13-cea-report-template_en_0	Clinical evaluation assessment report template	01.07.2020
MDCG_2020_3_Guidance on Significant Changes_Article 120	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	01.03.2020
MDCG_2019_9_Summay_of_Saftey and clinical performance_en_0	Summary of safety and clinical performance A guide for manufacturers and notified bodies	01.08.2019
MDCG_2019_5_legacy_devices_registration_eudamed_en_0	Registration of legacy devices in EUDAMED	01.04.2019
MDCG 2020-5 Guidance on Clinical Evaluation - Equivalence	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies	01.04.2020
MDCG 2020-13_Clinical evaluation assessment report template _eng	Clinical evaluation assessment report template	01.07.2020
MDCG 2018-1 v3 Guidance on basic UDI-DI and changes to UDI-DI-1	Guidance on BASIC UDI-DI and changes to UDI-DI	01.03.2020
MDCG_2021-19_Guidance_note_Integration_of_the_UDI	Guidance note integration of the UDI within an organisation's quality management system	01.07.2021
<b>Others</b>	<b>Designation</b>	<b>Date of issue</b>
NF S94-090	Medico-surgical equipment - Materials for ancillary positioning instruments for surgical instrument - Martensitic, precipitation hardening, austenitic and austeno-ferritic stainless steels	01.11.2005