

**Classification of dental medical devices  
according  
Regulation on Medical Devices 2017/745 (MDR)  
Annex VIII**

The Medical Device Regulation (MDR), applicable from 26 May 2021, has resulted in various changes with regard to classification. In this respect, the dental industry developed the following overview.

The basis for the compilation is:

- Art. 51 para. 1 MDR: devices are classified into classes I, IIa, IIb and III according to their intended purpose and the associated risks.
- Art. 52 para. 7 MDR: for certain Class I devices, limited involvement of the Notified Body in the conformity assessment procedure is required, specifically for devices placed on the market in a sterile condition (Class Is), for devices with a measuring function (Class Im) or for devices that are reusable surgical instruments (Class Ir).
- Annex VIII of the MDR (classification rules).
- Guidance from the Medical Device Coordination Group (MDCG) on the classification of medical devices (MDCG 2021-24, October 2021).

In individual cases, there may be different classifications. The reason for this is the assessment of the manufacturer on the intended purpose of the medical devices, which may differ for the same or similar products.

This classification list does not claim to be complete or legally valid. However, it is intended to provide assistance to manufacturers and notified bodies in the event of differences of opinion, with the aim of achieving uniform assessments throughout the dental industry.

<b>Product Description</b>	<b>Class</b>	<b>Classification according Annex VIII, MDR</b>	<b>Comments</b>
Adhesives for impression materials	I	Rule 5	
Adhesives	Ila	Rule 8	Placed „in the teeth“ See also bonder and cements
All-ceramics	Ila	Rule 8	
Alloys (for crowns, bridges, inlays, prosthetics)	Ila	Rule 8	Placed “in the teeth”
Amalgam	Ila	Rule 8	Placed in the teeth
Amalgam carrier	I	Rule 5	
Application-Dispenser	I	Rule 5	
Applications-syringes/cannulas	I	Rule 5	Invasive (e.g. for impression materials)
	Ila	Rule 6	Surgically-invasive (e.g. for cements)
Arcs, orthodontic	Ila	Rule 5, 3 <sup>rd</sup> indent	Long-term use
Articulation and occlusion materials	I	Rule 5	
	Ila	Rule 19	If nanomaterial is present
Artificial teeth	Ila	Rule 8	
Attachments	Ila	Rule 8	Fixed, long-term use
Bite registration materials	I	Rule 5	
	Ila	Rule 19	If nanomaterial is present
Blasting abrasives/Powder for dental cleaning including scaling, see prophylaxis powder	I	Rule 5 1 <sup>st</sup> or 2 <sup>nd</sup> indent	
Bleaching materials for tooth whitening	Ila	Rule 6 and Rule 7	Content of peroxide >6%
	Ila	Rule 19	If nanomaterial is present, potential for internal exposure is negligible
Bonder	Ila	Rule 8	Because the tooth is conditioned by insertion, the requirement „in the teeth“ is fulfilled (see also adhesives and cements)

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Bone file	Ir	Rule 6	
Bone mill	Ila	Rule 2	For channeling and storage of tissues for the purpose of insertion in the body
Bone replacement materials	Ila	Rule 8	Not resorbable
	III	Rule 8	resorbable
Bone rongeur, gouge pliers	Ir	Rule 5	
Bone scraper (without blade)	I	Rule 5	Invasive, transient use
Bone scraper (with blade)	Ir	Rule 6, 2 <sup>nd</sup> indent	Surgically invasive use
Brackets	Ila	Rule 5	Long-term use
Calcium hydroxide, Calcium salicylate, Calcium sulfate	Ila	Rule 8	
Cannulas for intraoral suction	Ila	Rule 5	Connection to an active device; invasive suction on tooth
	Ila	Rule 6	Surgical invasive suction on jaw bone
Cannulas for extraoral suction	I	Rule 1	
Cavity cleaning agents	Ila	Rule 6	
Cavity varnish	Ila	Rule 8	
Cements	Ila	Rule 8	(see also adhesives and bonder)
		Rule 19	If nanomaterial is present, potential for internal exposure is negligible
Chisel, Bone	Ir	Rule 6	Surgically-invasive
Clamp, artery / Haemostatic forceps	Ir	Rule 6	
Clamping wire	Ila	Rule 5, 3 <sup>rd</sup> indent	For long-term use, (see also braces)
Colours for staining	Ila	Rule 8	
	I	Rule 5	For removable protheses

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Compressor, dental compressed air	Ila	Rule 9	Production of energy
Conditioner	Ila	Rule 6	Transient use
Cotton rolls	I	Rule 5	
Crowns, dental crowns	Ila	Rule 8	
Crown and bridge materials (temporary, provisional)	Ila	Rule 7 or Rule 8	Depending on usage time
	Ila	Rule 19	If nanomaterial is present
Crown/Inlay remover	I	Rule 5	
Curette	Ir	Rule 6	Surgically-invasive
Data management systems for dental x-ray images	Ilb	Rule 11, 2 <sup>nd</sup> indent	
Dental casting alloys	Ila	Rule 5	Long-term use in oral cavity
Dental implants and abutments	Ilb	Rule 8	Long-term use, not placed “in the teeth”, therefore not class Ila
Dental implants, biological coated	III	Rule 8, 3 <sup>rd</sup> indent	If biological action is claimed
Dental syringe (impression material, rinsing)	I	Rule 5	
Dental treatment unit	Ila	Rule 9	
Dental operating light	I	Rule 13	
Denture adhesive (cream, powder)	Ila	Rule 21, 3 <sup>rd</sup> indent	Application in the oral cavity
Desensitizer	I	Rule 5, 1 <sup>st</sup> indent	For transient use
	I	Rule 5, 2 <sup>nd</sup> indent	For short-term use in the oral cavity
Diagnostic devices, dental	Ila	Rule 10	Devices for supporting dental diagnosis
Digital registration unit	I	Rule 13	
Disinfection devices	Ila	Rule 16	Cleaning-/disinfection devices used for disinfection of invasive products as end point of processing
	Ilb	Rule 16	

<b>Product Description</b>	<b>Class</b>	<b>Classification according Annex VIII, MDR</b>	<b>Comments</b>
Disinfections	IIa	Rule 16	Disinfection solutions used for disinfection of invasive products as end point of processing
	IIb	Rule 16	
Direction gauge/ Parallelization pin/ Positioning guide	I	Rule 5	
Drill sleeves, stop sleeves	I	Rule 5, first part of sentence	Products are used for transient use of X-ray verification of prosthetic requirements and for guiding surgical instruments. Invasive use in natural body openings.
Electrocautery	IIb	Rule 9	
Elevator, dental	Ir	Rule 6	Surgical invasive instrument, reprocessable
Endodontic filling material	IIa	Rule 8	Without drug substance
	III	Rule 14	With drug substance
Endodontic instruments	Ir	Rule 6	Surgically invasive instruments
	IIa	Rule 6	If used with a handpiece
Endodontic points	IIa	Rule 8	Analogue retention pins, see below
Endodontic rinsing solutions	IIa	Rule 6	Transient use, surgically-invasive product. If the rinsing solution contains chelators (EDTA or citric acid), it is a medical device. In case of NaOCL 5% it is in Germany pharmaceutical, in other EU-countries medical device.
Etching products (intraoral)	IIa	Rule 6	Transient use
	IIa	Rule 19	If nanomaterial is present
Excavator, dental	Ir	Rule 6	Surgical invasive instrument, reprocessable
Expansion screws	IIa	Rule 5, 3 <sup>rd</sup> indent	Long-term use

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Face bows	I	Rule 5	For long-term use
	Ila	Rule 5, 3 <sup>rd</sup> indent	
Filling materials (composite, glass-ionomer-cements, ceramic inlays, galvano inlays)	Ila	Rule 8	if nanomaterial is present, potential for internal exposure of nanomaterials is negligible
	Ila	Rule 19	
Filling materials (temporary, provisional)	Ila	Rule 7 or Rule 8	Depending on usage time
Forceps, dental	I	Rule 5	Intended use should explain the reasons for which there is no surgical use
Forceps (extraction-, tissue-, root splinter forceps)	Ir	Rule 6	Surgically invasive use; forceps, which come into contact with open wounds
Gauges for verification measurements, Calipper	I	Rule 5	
Hand instruments, surgical, e.g. spoons, root elevators, osteotomes, periotome, gingiva punch, bone scraper, luxation instruments, syndesmeotom	Ir	Rule 6	
Hand instruments, endodontic (endodontic probes, endodontic ruler/, endodontic spreaders, gutta-percha remover)	Ir	Rule 6	
Hand instruments, periodontal e.g. tunneling instruments, periodontal gingivectomy knife	Ir	Rule 6	
Handpieces and angled pieces (connected on motor)	Ila	Rule 9	
Handpiece with cold light	I	Rule 13	1r product, if reprocessing is required
High frequency devices, surgical	IIb	Rule 9	
Holding elements, orthodontic	Ila	Rule 5	Invasive product, used in the oral cavity
Imaging plate scanner	I	Rule 1 and Rule 13	

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Impression form, dental	I	Rule 5	
Impression material	Ila	Rule 19, 3 <sup>rd</sup> Indent  If applicable, additional Rule 4	If nanomaterial is present: Potential for internal exposure of nanomaterials is negligible  In contact with damaged mucosa  Without nanomaterial respectively without potential of internal exposure
Impression post	I	Rule 5	Different use possible: For transient use; No multiple use and no reprocessing; No contact with open wounds
	Ir	Rule 6	Surgically invasive use in cases, the product is used immediately after insertion of implants and might come into contact with blood and/or damaged mucosa
Impression tray		Rule 5 1 <sup>st</sup> Indent	Transient use; no surgically-invasive instrument, therefore no Class Ir product
Impression (not reprocessable)	I	Rule 5	
Insertion tools, manual -screw driver for bone screws/pins -membrane holder	I  I	Rule 5  Rule 6, 2 <sup>nd</sup> indent	Use with surgical-invasive indication
Interdental wedges	I	Rule 5	
Intraoral camera	I	Rule 13	Active medical device
Intraoral mirrors	I	Rule 5	
Instrument stand (bur holder)	I	Rule 1	Accessory for transport of (re-) processable and storage of rotary instruments
Knife holder	Ir	Rule 6	Surgically-invasive
Laser devices (for connection to laser handpieces)	Ilb	Rule 9	

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Liner	Ila	Rule 8	
	Ila	Rule 19	If nanomaterial is present
Lining materials (cavity)	Ila	Rule 8	Placed "in the teeth"
	Ila	Rule 19	If nanomaterial is present, potential for internal exposure of nanomaterials is negligible
Mallet, dental	I	Rule 5	
Materials against bruxism	I	Rule 5	
Materials for guided tissue regeneration	IIb	Rule 8	Not resorbable
	IIb	Rule 9	Resorbable
Matrices/-holder	I	Rule 5	
Microsurgical instruments (scissors, needle holder, forceps)	Ir	Rule 6	"Ir" in cases the instruments are being used surgically-invasive
Mixing cannula	I	Rule 5	Invasive use
	Ila	Rule 6	Surgically invasive-use
Mixing devices	I	Rule 1	If manual use
	I	Rule 13	If active medical device
Motor, air driven, turbines	Ila	Rule 9	
Mouth Gag, Mouth Gag Retractor	I	Rule 5	
Multifunctional handpieces	Ila	Rule 9	Intended for connection to medical devices class Ila
Needle holder	Ir	Rule 6	
Osteotome	Ir	Rule 6	Surgically-invasive
Other devices and materials for the preparation of custom-made dental devices	I	Rule 1	Devices according EMDN-Nomenclature under Q010699 (materials for the preparation of custom-made dental devices – other)
Paper points for root-canal cleaning and drying	Ila	Rule 5	



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Parapulpal pins	Ila	Rule 8	Used in gum openings, but not „surgically-invasive“. Product does not penetrate the body surface, therefore not class 1r.
Patient chair, dental	I	Rule 13	Active product, not suitable for administer
Periodontal probe	I	Rule 5	
Photographic chemicals for x-ray film development	I	Rule 1	
Pit and fissure sealant	Ila	Rule 5 or Rule 8	
Pivot teeth	Ila	Rule 8	
Polisher, polishing discs (connected to a handpiece)	Ila	Rule 5 last sentence	Connection to an active device class Ila Rule 19 is not applicable, since particles are contained in a bound manner
Polishing pastes	I	Rule 5, 1 <sup>st</sup> indent	Short-term use in the oral cavity; Product is used for surface smoothing. Application to polishing rollers for spreading on the area to be polished. Subsequent suction or rinsing, therefore no absorption from the body, therefore no application of rule 21.
Polishing strips, separating strips, interproximal strips	I	Rule 5, 2 <sup>nd</sup> indent	No connection to an active device; no active devices; Strips are no surgical instruments, therefore not class 1r, unless placed in the market sterile
Polymer materials for dental trays	I	Rule 5	Transient or short-term use
	Ila	Rule 5	Long-term use
Polymerisation lamps	Ila	Rule 9	If intended to a medical device class Ila
Polymerizing devices for hardening	I	Rule 13	Stand alone
	Ila	Rule 9	If connection for medical devices of class Ila is present

Product Description	Class	Classification according Annex VIII, MDR	Comments
Powder devices for dental treatment	Ila	Rule 12	
Powder jet handpieces	Ila	Rule 9	Air-driven handpiece, used for therapeutic purposes through radiated cleaning powder
Pressure air cleaner, drying of teeth	Ila	Rule 12	
Prophylaxis powder, blasting powder, dental Used together with powder jet instruments (see below)	I	Rule 5, 1 <sup>st</sup> or 2 <sup>nd</sup> indent	Transient use or in case of application in the oral cavity, also in the case of subgingival application class 1 and rule 5, because there is no surgically invasive use
	Ila	Rule 19	if nanomaterial is present
Prosthetic materials	Ila	Rule 5	
Protected varnish (see varnishes)	I	Rule 5	
Pulp capping material	Ila	Rule 8	Without drug substance
	III	Rule 14	With drug substance
Pulp vitality measuring device	Ila	Rule 10	
Ratchet -torque wrench -ratchet wrench insert	I	Rule 5	If the intended use is „manual insertion of implants or fixing of abutments up to the intended torque. No 1r device, because product does not saw and scratch and does not penetrate through the mucosa, therefore in case of this intended use not surgically invasive.
	Ir	Rule 6	If the product is used during a surgical treatment and comes into contact with injured mucosa, then the application is surgically invasive („worst-case-view“)
Relining materials for prostheses	Ila	Rule 21	Application in the oral cavity
Retention pins / root posts	Ila	Rule 8	
Retraction cords, -rings	I	Rule 5	Without drug substance
	III	Rule 14	With drug substance

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Retraction paste	Ila	Rule 4	Due to haemostatic effect
	Ila	Rule 19	If nanomaterial is present
Retractor	Ir	Rule 6	Surgically-invasive
Rotary Instruments, connected to a handpiece, invasive	Ila	Rule 5	
Rotary Instruments, connected to an active handpiece, surgically invasive	Ila	Rule 6	
Rubber Dam, Rubber Dam Frame Support structure for rubber dam	I	Rule 5	
Scaler, powered (ZEG handpiece)	Ila	Rule 9	Handpieces, used electrically or air-driven, in conjunction with syringes for dental treatment
Scaler, ultrasound	Ila	Rule 12	
Silanisation materials	Ila	Rule 8	
Spatula	I	Rule 5	
Spoons for gels	I	Rule 5	
Sprays	I	Rule 5	
-Anti fog sprays for intraoral mirrors	I	Rule 5	
-Occlusion sprays	Ila	Rule 19	If nanomaterial is present: Potential for internal exposure of nanomaterials is negligible
-intraoral scan sprays	Ila	Rule 21	Application in the oral cavity
-Powder sprays	Ila	Rule 19	Potential for internal exposure of nanomaterials is negligible
Sterile material container	I	Rule 1	
Sterilizer	I	Rule 13	
Suction devices, dental	Ila	Rule 12	
Suction equipment	Ila	Rule 12	Active MD for removal of body liquids from the body
Suction equipment - cannula	Ila	Rule 5	Rule 5 last sentence: connection to an active device

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Suture materials	Ila	Rule 7	Not resorbable
	III	Rule 7, 14 or 18	Resorbable, with drugs
Syringes, reusable	I	Rule 5	In the case of invasive application
Syringes, single-use, sterile	Ila	Rule 6	
Syringes with anaesthetic (cartridge syringe) without injection needle	I	Rule 5	
Tamponades	I	Rule 5	Without drug substance
	III	Rule 14	With drug substance
Tooth crowns	Ila	Rule 8	
Tooth forming devices (consisting of bonder, brackets, wires)	Ila	Rule 5 3 <sup>rd</sup> indent	Long-term use
Turbines, dental	Ila	Rule 9	High-speed turbine handpiece, air-driven
Ultrasonic device for dental cleaning	Ila	Rule 9	
Varnishers (protective varnishers, fluoriding varnishers)	I	Rule 5, 1 <sup>st</sup> or 2 <sup>nd</sup> indent	Short-term or transient use
Veneer, Veneering materials	Ila	Rule 8	If placed "in the teeth"
	Ilb	Rule 8	
Waxes, intraoral	I	Rule 5	
Wires, orthodontic (wires, orthodontic arcs for orthodontics)	Ila	Rule 5, 3 <sup>rd</sup> indent	Long-term use
Wound dressing in the oral cavity	I	Rule 5	
x-ray devices, dental	Ilb	Rule 10	
x-ray film	Ila	Rule 17	
x-ray film developer	I	Rule 1	
x-ray equipment	Ilb	Rule 10	
x-ray image viewer, dental	I	Rule 13	
x-ray imaging plate, dental	Ila	Rule 17	

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x-ray sensor, dental	Ila	Rule 17	

Cologne, February 2022  
FIDE-European Dental Industry