



# EU Technical Documentation Assessment Certificate



This is to certify that the company

## MANI MEDICAL GERMANY GmbH

Hertha-Sponer-Straße 2  
61191 Rosbach v.d. Höhe  
Germany

SRN: DE-MF-000009196

has established and maintains the required Technical Documentation in accordance with

### Annex IX, Chapter II of the Regulation (EU) 2017/745

**Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Devices of class IIa and IIb listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	230469 MDR2017B
Certificate ID	1000135352
Effective date	2023-09-21
Expiry date	2028-01-11
Frankfurt am Main,	2023-09-21



## DQS Medizinprodukte GmbH

Sigrid Uhlemann  
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Head of Certification Body  
(active medical devices)

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Head of Certification Body  
(non-active medical devices)



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745  
of the Council concerning medical devices with the Identification Number 0297.  
The validity of this certificate can only be verified by the QR-code.



**Annex to EU Technical Documentation Assessment Certificate**  
**SRN of Manufacturer: DE-MF-000009196**  
**Certificate ID: 1000135352**

**Device categories and variants covered by this certificate:**

Device category: **MDN 1103 Non-active dental implants and dental materials**  
Product name: Dental-Verblendung  
Models: Resin facing material  
Risk classification: IIa  
Basic-UDI-DI: +D933 32 00001W  
Intended purpose: Resin facing materials are composites used for covering different framework materials for the design of dental restorations.

Device category: **MDN 1103 Non-active dental implants and dental materials**  
Product name: Verbundwiederherstellungsmaterial, dental  
Models: Dental filling materials on composite basis  
Risk classification: IIa  
Basic-UDI-DI: +D933 11 00001T  
Intended purpose: Dental filling materials on composite basis are used to build up or to preserve tooth structures.

Device category: **MDN 1103 Non-active dental implants and dental materials**  
Product name: Wiederherstellungsmaterial, dental, Krone und Brücke  
Models: Temporary crown and bridge materials  
Risk classification: IIa  
Basic-UDI-DI: +D933 30 00001U  
Intended purpose: Temporary crown and bridge materials are used for the fabrication of individual temporary crowns and bridges.

Device category: **MDN 1103 Non-active dental implants and dental materials**  
Product name: Verbundwiederherstellungsmaterial, dental, sonstige  
Models: Fixing composite/root pin cement  
Risk classification: IIa  
Basic-UDI-DI: +D933 17 00001Z  
Intended purpose: Fixing composites/root pin cements are used for the adhesive, permanent bonding of restorative materials to restorative materials, to hard tooth structure or to a denture base, or to secure root pins in the root canal.

Device category: **MDN 1103 Non-active dental implants and dental materials**  
Product name: Zahnprothese, Klebmittel  
Models: Dentin and enamel adhesives  
Risk classification: IIa  
Basic-UDI-DI: +D933 23 00001W  
Intended purpose: The product group "Dentin and enamel adhesives" comprises bonding agents for the application in adhesive restorative dentistry.



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Device category: **MDN 1103 Non-active dental implants and dental materials**  
Product name: Zubehörkit, Wiederherstellungsmaterial, dental  
Models: Dental colors for individualization  
Risk classification: IIa  
Basic-UDI-DI: +D933 33 00001X  
Intended purpose: Dental colors for individualization are composite-based colors that are used to individualize or characterize a wide variety of dental materials.

Device category: **MDN 1103 Non-active dental implants and dental materials**  
Product name: Wiederherstellungsmaterial, dental  
Models: Millable CAD/CAM materials  
Risk classification: IIa  
Basic-UDI-DI: +D933 31 00001V  
Intended purpose: The millable CAD/CAM materials are intended for the fabrication of dental prosthetic restorations using dental milling systems. The millable CAD/CAM materials are intended for use by the dental technician in a dental laboratory. Depending on the type of material, the product can be used to create temporary or permanent dental restorations.

Device category: **MDN 1209 Non-active non-implantable dental materials**  
Product name: Zahnprothese, Klebemittel  
Models: Attachment glue  
Risk classification: IIa  
Basic-UDI-DI: +D933 16 00001Y  
Intended purpose: Attachment glues are used for the adhesive, permanent bonding of telescopic or conical crowns or prefabricated retaining elements to the framework material.

Device category: **MDN 1209 Non-active non-implantable dental materials**  
Product name: Zahnprothesenbasis- Harz  
Models: Light-curing denture lacquer  
Risk classification: IIa  
Basic-UDI-DI: +D933 28 00001.  
Intended purpose: The light-curing denture lacquer is used to chemically smooth the surface of a denture base after finishing.

Device category: **MDN 1209 Non-active non-implantable dental materials**  
Product name: Zahnprothesenbasis-Harz, selbstaushärtend bzw. Zahnprothesenbasis-Harz, wärmeaushärtend bzw. Zahnprothesenunter-fütterung, hart  
Models: Denture base materials  
Risk classification: IIa  
Basic-UDI-DI: +D933 29 00001  
Intended purpose: Denture base materials are intended for the fabrication of splints, partial dentures, full dentures and model dentures.



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Device category:	<b>MDN 1209 Non-active non-implantable dental materials</b>
Product name:	Zahnbleichmittel
Models:	Dental bleaching gel
Risk classification:	Ia
Basic-UDI-DI:	+D933 13 00001V
Intended purpose:	A dental bleaching gel is a product used to brighten teeth that are devitalized or discoloured by diseases, injuries, medicines or iatrogenically.
Device category:	<b>MDN 1209 Non-active non-implantable dental materials</b>
Product name:	Dental-Ätzflüssigkeit
Models:	Dental etching gel
Risk classification:	Ia
Basic-UDI-DI:	+D933 20 00001T
Intended purpose:	Dental etching gel is used to etch enamel and/or dentin.
Device category:	<b>MDN 1209 Non-active non-implantable dental materials</b>
Product name:	Dental-Schienenmaterial
Models:	Glass fibres with light curing resin matrix
Risk classification:	Ia
Basic-UDI-DI:	+D933 10 00001S
Intended purpose:	The areas of application for glass fiber include the manufacture of glass fiber-reinforced bridges and implant dentures, periodontal splints to stabilize loose teeth, the use as space maintainers to protect gaps between teeth, and the use as orthodontic retainers to stabilize the position of teeth after an orthodontic treatment.
Device category:	<b>MDN 1209 Non-active non-implantable dental materials</b>
Product name:	Zement, orthodontisch
Models:	Fixing composite for orthodontic attachments
Risk classification:	Ia
Basic-UDI-DI:	+D933 19 00001.
Intended purpose:	Fixing composites for orthodontic attachments are materials for the adhesive bonding of orthodontic retainer elements.
Device category:	<b>MDN 1209 Non-active non-implantable dental materials</b>
Product name:	Zahnprothese, Klebmittel
Models:	Bonding agent
Risk classification:	Ia
Basic-UDI-DI:	+D933 21 00001U
Intended purpose:	Bonding agents are used to bond various restorative materials to the framework material.



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Device category: **MDN 1209 Non-active non-implantable dental materials**  
Product name: Zahnprothese, Klebemittel  
Models: Orthodontic bonding agent  
Risk classification: IIa  
Basic-UDI-DI: +D933 24 00001X  
Intended purpose: Orthodontic bonding agents are materials for conditioning hard tooth structures and other restorative surfaces in an orthodontic treatment.

Device category: **MDN 1209 Non-active non-implantable dental materials**  
Product name: Gummischutz, dental  
Models: Light-curing dental dam  
Risk classification: IIa  
Basic-UDI-DI: +D933 15 00001X  
Intended purpose: Light-curing material for covering the gingiva or for isolating it from the teeth to be treated during in-office bleaching.

Device category: **MDN 1209 Non-active non-implantable dental materials**  
Product name: Dental-Verblendung  
Models: Framework covering material  
Risk classification: IIa  
Basic-UDI-DI: +D933 27 00001-  
Intended purpose: Framework covering materials are composite-based materials for covering different framework materials in preparation for subsequent veneering with veneering composite or denture resin.

### Examinations and tests performed:

230469 A209421MED\_02\_Fräsbare CAD/CAM-Materialien dated 11.10.2022  
230469 A209421MED MDR2017B Tender Fiber dated 17.05.2023

### Further conditions for or limitations to the validity of the certificate:

n/a

### Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-01-12	170781917	Optimizing the purpose of the products
02	2023-04-13	1000117650	Addition of the product Tender Fiber and further products with MDN 1209
03	2023-06-28	1000123322	New company name and address change