EU Quality Management 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, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III 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 Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

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

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	230469 MDR2017Q
Certificate ID	1000171437
Effective date	2024-05-23
Expiry date	2028-01-11
Frankfurt am Main,	2024-05-23

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000009196
Certificate ID: 1000171437

Device categories and variants covered by this certificate:

Device category:	**MDN 1103 Non-active dental implants and dental materials**
Product name:	Resin facing material
Risk classification:	IIa
Basic-UDI-DI:	++D93303200001DG
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:	Dental filling materials on composite basis
Risk classification:	IIa
Basic-UDI-DI:	++D93301100001BZ
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:	Temporary crown and bridge materials
Risk classification:	IIa
Basic-UDI-DI:	++D93303000001CN
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:	Fixing composite/root pin cement
Risk classification:	IIa
Basic-UDI-DI:	++D93301700001EF
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:	Dentin and enamel adhesives
Risk classification:	IIa
Basic-UDI-DI:	++D93302300001DC
Intended purpose:	The product group "Dentin and enamel adhesives" comprises bonding agents for the application in adhesive restorative dentistry.

Device category:	**MDN 1103 Non-active dental implants and dental materials**
Product name:	Dental colors for individualization
Risk classification:	IIa
Basic-UDI-DI:	++D93303300001DV
Intended purpose:	Dental colors for individualization are composite-based colors that are used to individualize or characterize a wide variety of dental materials.

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Device category:	**MDN 1103 Non-active dental implants and dental materials**
Product name:	Millable CAD/CAM materials
Risk classification:	IIa
Basic-UDI-DI:	++D93303100001D3
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:	Attachment glue
Risk classification:	IIa
Basic-UDI-DI:	++D93301600001E2
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:	Light-curing denture lacquer
Risk classification:	IIa
Basic-UDI-DI:	++D93302800001FD
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:	Denture base materials
Risk classification:	IIa
Basic-UDI-DI:	++D93302900001FS
Intended purpose:	Denture base materials are intended for the fabrication of splints, partial dentures, full dentures and model dentures.

Device category:	**MDN 1209 Non-active non-implantable dental materials**
Product name:	Dental bleaching gel
Risk classification:	IIa
Basic-UDI-DI:	++D93301300001CT
Intended purpose:	A dental bleaching gel is a product used to brighten teeth that are devitalized or discoloured by diseases, injuries, medicines or iatrogenically.

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Device category:	**MDN 1209 Non-active non-implantable dental materials**
Product name:	Dental etching gel
Risk classification:	IIa
Basic-UDI-DI:	++D93302000001C5
Intended purpose:	Dental etching gel is used to etch enamel and/or dentin.

Device category:	**MDN 1209 Non-active non-implantable dental materials**
Product name:	Glass fibres with light curing resin matrix
Risk classification:	IIa
Basic-UDI-DI:	++D93301000001BL
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:	**MDN 1209 Non-active non-implantable dental materials**
Product name:	Fixing composite for orthodontic attachments
Risk classification:	IIa
Basic-UDI-DI:	++D93301900001F9
Intended purpose:	Fixing composites for orthodontic attachments are materials for the adhesive bonding of orthodontic retainer elements.

Device category:	**MDN 1209 Non-active non-implantable dental materials**
Product name:	Bonding agent
Risk classification:	IIa
Basic-UDI-DI:	++D93302100001CJ
Intended purpose:	Bonding agents are used to bond various restorative materials to the framework material.

Device category:	**MDN 1209 Non-active non-implantable dental materials**
Product name:	Orthodontic bonding agent
Risk classification:	IIa
Basic-UDI-DI:	++D93302400001DR
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:	Light-curing dental dam
Risk classification:	IIa
Basic-UDI-DI:	++D93301500001DM
Intended purpose:	Light-curing material for covering the gingiva or for isolating it from the teeth to be treated during in-office bleaching.

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Device category:	**MDN 1209 Non-active non-implantable dental materials**
Product name:	Framework covering material
Risk classification:	IIa
Basic-UDI-DI:	++D93302700001EY
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_01 dated 30.05.2022
230469 A213383MED_01 dated 21.09.2023
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	170781916	Optimizing the Purpose of the products
02	2023-04-13	1000117656	Addition of product Tender Fiber and further products with product category MDN 1209
03	2023-06-28	1000123333	New company name and address change
04	2023-09-21	1000135355	New certificate template and correction of the Basic-UDI-DI