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.

For placing of devices of class IIa, IIb or III 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	1000135355
Effective date	2023-09-21
Expiry date	2028-01-11
Frankfurt am Main,	2023-09-21

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
(active medical devices)

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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: 1000135355

Device categories covered by this certificate:

Device category:	**MDN 1103 Non-active dental implants and dental materials**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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.

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

Device category:	**MDN 1209 Non-active non-implantable dental materials**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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

Further conditions for or limitations to the validity of the certificate:
The manufacturer’s quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

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