CERTIFICATE

This is to certify that the company

MANI MEDICAL GERMANY GmbH

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

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design and development, manufacture, and distribution of medical materials, equipment for dental offices and dental labs according to annex:
- CND

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	230469 MDSAP16
Certificate unique ID	1000135367
Effective date	2023-09-21
Expiry date	2024-04-15
Frankfurt am Main	2023-09-21

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 230469 MDSAP16
Certificate unique ID: 1000135367
Effective date: 2023-09-21

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Audited site	**REPs FEI No.: site scope and country-specific requirements**
230469 **MANI MEDICAL GERMANY GmbH** Hertha-Sponer-Straße 2 61191 Rosbach v. d. Höhe Germany	Design and development, manufacture, and distribution of medical materials, equipment for dental offices and dental labs according to annex: **-CND** **REPs FEI No.: 002487**

Annex to certificate
Certificate registration No.: 230469 MDSAP16
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Denture base materials
Temporary crown and bridge materials
Dental filling materials on composite basis
Resin facing material
Light-curing denture lacquer
Dentin bonding
Dental bleaching gel
Fixing composite / root pin cement
Ceramic repair material
Attachment glue
Dental etching gel
Glass fibres with light curing resin matrix
Fixing composite for orthodontic attachments
Dentin and enamel adhesives
Dental colors for individualization
Framework covering material
Bonding agent
Millable CAD / CAM materials
Orthodontic bonding agent

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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821