CERTIFICATE

This is to certify that the company

DETAX GmbH

Carl-Zeiss-Straße 4
76275 Ettlingen
Germany

with the organizational units/sites as listed in the annex

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

Scope of certification:
Design, development, manufacture and distribution of dental impression materials, soft relining materials, materials for temporary crowns and bridges, silicone lacquers, ear impression materials, ear mould silicones, acrylic ear mould resins, orthopedic casting compounds, dental cements, universal dental resin.
- AUS (a), BRA; CND, JPN, USA (a, b, c, d)

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.	352715 MDSAP16
Certificate unique ID	170782058
Effective date	2023-09-18
Expiry date	2026-09-17
Frankfurt am Main	2023-07-24

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 352715 MDSAP16
Certificate unique ID: 170782058
Effective date: 2023-09-18

DETAX GmbH

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Audited site	REPs FEI No.: site scope and country-specific requirements
352715 **DETAX GmbH** Carl-Zeiss-Straße 4 76275 Ettlingen Germany	Design, development, manufacture and distribution of dental impression materials, soft relining materials, materials for temporary crowns and bridges, silicone lacquers, ear impression materials, ear mould silicones, acrylic ear mould resins, orthopedic casting compounds, dental cements, universal dental resin. **- AUS (a), BRA; CND, JPN, USA (a, b, c, d)** **REP´s FEI No.: F000636**

Annex to certificate
Certificate registration No.: 352715 MDSAP16
Certificate unique ID: 170782058
Effective date: 2023-09-18

DETAX GmbH

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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