CERTIFICATE

This is to certify that the company

Polident d.o.o.

Volčja Draga 42
5293 Volčja Draga
Slovenia

with the organizational units/sites as listed in the annex

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

Scope of certification:
Design and Development, Manufacturing and Distribution of Artificial teeth and CAD/CAM discs
AUS (a), CND, 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.	092246 MDSAP16
Certificate unique ID	170772178
Effective date	2020-10-30
Expiry date	2023-10-29
Frankfurt am Main	2020-10-30

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

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Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.mydqs.com/en/customers/customer-database.html to validate this certificate.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 092246 MDSAP16
Certificate unique ID: 170772178
Effective date: 2020-10-30

Polident d.o.o.

Volčja Draga 42
5293 Volčja Draga
Slovenia

Audited site	DUNS No., site scope and country-specific requirements
Polident d.o.o. Volčja Draga 42 5293 Volčja Draga Slovenia	Design and Development, Manufacturing and Distribution of Artificial teeth and CAD/CAM discs **AUS (a), CND, USA (a, b, c, d)** **DUNS No.: 644778409**

Annex to certificate
Certificate registration No.: 092246 MDSAP16
Certificate unique ID: 170772178
Effective date: 2020-10-30

Polident d.o.o.

Volčja Draga 42
5293 Volčja Draga
Slovenia

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. 16/2013 RDC ANVISA n. 23/2012 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