# 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 | 1000129515 |
| Effective date | 2023-10-30 |
| Expiry date | 2026-10-29 |
| Frankfurt am Main | 2023-10-11 |

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

**DQS Medizinprodukte GmbH**

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

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Tel. +49 (0) 69 95427-300, info-med@dqs.de
**DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.**
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.
**The validity of this certificate can only be verified by the QR-code.**



413.01 Version 6.0

**Annex to certificate**
**Certificate registration No.: 092246 MDSAP16**
**Certificate unique ID: 1000129515**
**Effective date: 2023-10-30**

# Polident d.o.o.

Volčja Draga 42
5293 Volčja Draga
Slovenia

| Audited site | REPs FEI No.: site scope and country-specific requirements |
|---|---|
| **092246**<br>**Polident d.o.o.**<br>Volčja Draga 42<br>5293 Volčja Draga<br>Slovenia | Design and Development, Manufacturing and Distribution of Artificial teeth and CAD/CAM discs<br>-**AUS (a), CND, USA (a,b,c,d)**<br>**REPs FEI No.: F004982** |

# Annex to certificate
# Certificate registration No.: 092246 MDSAP16
# Certificate unique ID: 1000129515
# Effective date: 2023-10-30

## 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<br>(b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure |
| BRA | Brazil | RDC ANVISA n. 665/2022<br>RDC ANVISA n. 551/2021<br>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<br>Japan PMD Act (as applicable) |
| USA | United States | (a) 21 CFR Part 803<br>(b) 21 CFR Part 806<br>(c) 21 CFR Part 807<br>(d) 21 CFR Part 820<br>(e) 21 CFR Part 821 |