

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Polident d.o.o.

Main Site: Volcja Draga 42

5293 Volcja Draga, Slovenia (FIN F008916)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)

The management system is applicable to:

Design and development, manufacturing and distribution of artificial teeth and CAD/CAM discs

Organization was certified by another Certification Body before 1/23/2026.

Certificate Number:

0236641

Revision Level: 01

Date of Certification Decision:

2026-10-05

Certification Effective Date:

2026-10-29

Certification Expiry Date:

2029-10-29



intertek

A handwritten signature in black ink that reads "Mark Thomas".

Mark Thomas

Executive Vice President

Assurance, Sustainability, AgriWorld & Food

Intertek Testing Services NA, Inc.

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