

POLISH CENTRE FOR
TESTING AND CERTIFICATION

No. 1434-MDR-018/2024

**of the EU technical documentation assessment with the requirements
of Chapter II of Annex IX to the Regulation (EU) 2017/745
issued for medical devices manufactured by:**

UAB Prodenta

Vytauto st. 42, LT-68295, Marijampole, Lithuania
Single Registration Number (SRN): LT-MF-000022508

Polish Centre for Testing and Certification S.A. (Notified Body no. 1434) certifies that the technical documentation of the medical devices covered by this certificate complies with the requirements specified in Annexes II and III to the Regulation (EU) 2017/745. Details of the devices covered by this certificate are described on the following pages. The technical documentation report referenced below summarises the result of the assessment and includes reference to the relevant common specifications, harmonized standards and test reports.

Report no.: **S/027/BM/2023**

Validity of the Certificate: from 18.12.2024 to 17.12.2029

The date of issue of the Certificate: 18.12.2024

Tomasz Koebel
Head of Medical Devices
Certification Department

Certificate bears the qualified signature PCBC S.A.
Warsaw, 18/12/2024

FBM-R-24-MDR-E/7 of 27.09.2024

Polish Centre for Testing and Certification

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**of the Assessment of the technical documentation with the requirements
of Chapter II of Annex IX to the Regulation (EU) 2017/745**

Devices covered by the certificate: Probase ABUTMENT KIT

Risk Classification: IIb

Basic Code UDI-DI: 477905259000AS2J

Intended use: Prodenta Probase® ABUTMENT KIT (consisting of abutment and screw) is a prosthetic component which connects directly to dental implant. It is intended for use as a part in prosthetic rehabilitation by having all mechanical functions to fit on the implant and functions related with esthetic results for a final restoration. Probase® Screw is used to secure Probase® Abutment to the implant providing a low friction surface, producing a high clamping force between the abutment and the implant

Certificate validity conditions and/or limitations: not applicable

Revision History including Changes: 1/18.12.2024/S/027/BM/2023

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