

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2607846-1

Manufacturer: APOLLO IMPLANT COMPONENTS Spółka z ograniczoną odpowiedzialnością
ul. Konopna 16
95-200 Pabianice
Poland

EUDAMED Single
Registration No.: PL-MF-000023711

Products: Products of class IIb:
P01020180 - DENTAL IMPLANTS AND ACCESSORIES
DENTAL IMPLANTS
Limited to prosthetic abutments for dental
implants and related screws, healing abutments.

Authorized representative(s): Not applicable.

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification.	2023-12-20
1	Change of the legal entity of the manufacturer.	2024-09-12

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.


Report No.: 84977894-10

Effective date: 2024-09-13

Expiry date: 2028-12-19

Issue date: 2024-09-13

This certificate can be validated on <https://www.certipedia.com>


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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

