EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapters I and 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: P01020101 - ODONTOLOGICAL PROSTHESES. DENTAL IMPLANTS. Prosthetic abutments for dental implants and related screws.
Authorized representative(s):	Not applicable.

The Notified Body hereby declares that the requirements of Annex IX, Chapter I 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.:	84984491-20
Effective date:	2025-09-25
Expiry date:	2028-12-19
Issue date:	2025-09-25

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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ul. Konopna 16
95-200 Pabianice
Poland

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-12-20
1	Change of the legal entity of the manufacturer	2024-09-12
2	Change of the scope of the certificate	2025-09-25