Certificate

Certificate No.:	MD 2607846 1-1
Manufacturer:	**Apollo Implant Components Sp. z o.o.** ul. Konopna 16 95-200 Pabianice Poland
REPs Facility ID:	F008330
Certification criteria:	ISO 13485:2016 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, 21 CFR 821
Scope:	Design and development, manufacture and distribution of non-sterile dental abutments, non-sterile dental scan abutments for dental implants and non-sterile instruments used in dental reconstruction procedure.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	84983760-50
Issue Date:	2025-07-17
Effective Date:	2025-07-17
Expiry Date:	2028-07-16

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dominika Książek
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

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