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POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. 1434-MDR-014/2026

of Conformity of the Quality Management System EU with the requirements of Chapter I of the Annex IX to the Regulation (EU) 2017/745 issued to manufacturer:

MEDGAL Sp. z o.o.
Niewodnicka 26A, 16-001 Księżyno, Poland

Polish Centre for Testing and Certification S.A. (Notified Body no. 1434) certifies that the manufacturer has established, documented and implemented a Quality Management System as described in article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details of the devices covered by this certificate are described on the following pages. The Report referenced below summarizes the result of the assessment and includes reference to the relevant common specifications, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I to the regulation mentioned above. The certified Quality Management System is subject to periodical surveillance by PCBC S.A.

Report no.: **S/262/BM/2024**

Validity of the Certificate: from 26.05.2026 to 25.05.2031
The date of issue of the Certificate: 26.05.2026

Agnieszka Bukowska
Elektronicznie podpisany przez Agnieszka Bukowska
Data: 2026.05.26 16:41:14 +02'00'

Certificate bears the qualified signature PCBC S.A.
Warsaw, 26/05/2026

Polish Centre for Testing and Certification 469, Puławska Street, PL-02-844 Warsaw tel.: +48 22 45 46 200, pcbc@pcbc.gov.pl

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of Conformity of the Quality Management System EU with the requirements of Chapter I of the Annex IX to the Regulation (EU) 2017/745

Devices covered by the certificate: Custom Made Implants

Risk Classification: III

EMDN Code: P09080301, P09080302, P09080303

Intended use: extensive lesions and bone defects within the pelvis, advanced degenerative changes in the hip joint (primary osteoarthritis, secondary osteoarthritis, avascular necrosis of the femoral head), joint destruction due to other causes: femoral neck fractures, post-traumatic conditions following pelvic fractures, bone defects associated with neoplastic processes, pelvic injuries where standard treatment methods would be inadequate, carry too high a risk or be impossible to perform, other indications arising from medical consultation

Certificate validity conditions and/or limitations: NA.

Revision History including Changes: 1/26.05.2026/S/262/BM/2024

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