

POLISH CENTRE FOR
TESTING AND CERTIFICATION

No. 1434-MDR-043/2025

**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:**

LfC Sp. z o.o.

ul. Kożuchowska 41, 65-364 Zielona Góra, Polska

Single Registration Number (SRN): PL-MF-000024898

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/018/BM/2025**

Validity of the Certificate: from 07.11.2025 to 06.11.2030

The date of issue of the Certificate: 07.11.2025

Certificate bears the qualified signature PCBC S.A.
Warsaw, 07.11.2025

FBM-R-31-MDR-E of 07.11.2025

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CERTIFICATE

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

EMDN Code: According to Annex

Revision History including Changes: 1/ 07.11.2025/ S/018/BM/2025

[illegible]

Kod EMDN	Generic name by code:
P090199	PROSTHESES, SHOULDER - OTHERS
P090203	PROSTHESES, ELBOW, HUMERAL COMPONENTS
P090204	PROSTHESES, ELBOW, RADIAL COMPONENTS
P090299	PROSTHESES, ELBOW - OTHERS
P090303	PROSTHESES, WRIST, CARPAL COMPONENTS
P090304	PROSTHESES, WRIST, RADIAL/ULNAR COMPONENTS
P090399	PROSTHESES, WRIST - OTHERS
P090403	PROSTHESES, HAND, INTERPHALANGEAL COMPONENTS
P090404	PROSTHESES, HAND, TRAPEZIUM-METACARPAL COMPONENTS
P090499	PROSTHESES, HAND - OTHERS
P090503	PROSTHESES, ANKLE, TALAR COMPONENTS
P090504	PROSTHESES, ANKLE, TIBIAL COMPONENTS
P090505	PROSTHESES, ANKLE, TIBIO-TARSAL COMPONENTS
P090599	PROSTHESES, ANKLE - OTHERS
P090603	PROSTHESES, FOOT, INTERPHALANGEAL COMPONENTS
P090604	PROSTHESES, FOOT, METATARSALPHALANGEAL COMPONENTS
P090605	FOOT ENDORTHOSIS
P090699	PROSTHESES, FOOT - OTHERS
P09070101	SPINAL CAGES
P09070199	SPINAL FUSION SYSTEMS - OTHERS
P090702	SPINE DISC, DISPLACEMENT SYSTEMS
P09070201	PROSTHESES, SPINE DISC
P09070301	PROSTHESES, CERVICAL FIXATION SYSTEMS
P09070302	THORACOLUMBOSACRAL SPINE, FIXATION SYSTEMS
P09070304	SPINE FIXATION SYSTEMS, CONNECTORS
P09070305	SPINAL STABILIZERS DINAMIC TYPE
P09070399	PROSTHESES, SPINAL FIXATION OR STABILIZATION SYSTEMS - OTHERS

Certificate bears the qualified signature.
Warsaw, 07.11.2025

Kod EMDN	Generic name by code:
P090799	PROSTHESES AND SYSTEMS FOR SPINE STABILIZATION - OTHERS
P090803010101	CEMENTED METAL ACETABULAR CUPS - PRIMARY SURGERY
P090803010199	CEMENTED ACETABULAR CUPS - PRIMARY SURGERY - OTHERS
P090803010201	UNCEMENTED METAL ACETABULAR CUPS - PRIMARY SURGERY
P090803010203	UNCEMENTED ONE-PIECE METAL ACETABULAR CUPS - PRIMARY SURGERY
P090803010299	UNCEMENTED ACETABULAR CUPS - PRIMARY SURGERY - OTHERS
P09080302	HIP RESURFACING ACETABULAR CUPS
P0908030301	CEMENTED ACETABULAR CUPS - REVISION SURGERY
P0908030302	UNCEMENTED ACETABULAR CUPS - REVISION SURGERY
P09080304	HIP PROSTHESIS - ACETABULAR INSERTS
P0908030403	HIP PROSTHESIS - METAL ACETABULAR INSERTS
P0908030499	HIP PROSTHESIS - ACETABULAR INSERTS - OTHERS
P0908030501	DOUBLE-MOBILITY ACETABULAR CUPS
P090803050101	CEMENTED DOUBLE-MOBILITY ACETABULAR CUPS
P090803050102	UNCEMENTED DOUBLE-MOBILITY ACETABULAR CUPS
P0908030502	DOUBLE-MOBILITY ACETABULAR COMPONENTS - INSERTS
P09080306	PRE-ASSEMBLED ACETABULAR COMPONENTS (ACETABULAR CUP + INSERT)
P0908030699	PRE-ASSEMBLED ACETABULAR COMPONENTS - OTHERS
P090804010101	NONMODULAR STRAIGHT CEMENTED FEMORAL STEMS - PRIMARY SURGERY
P090804010102	NONMODULAR ANATOMIC CEMENTED FEMORAL STEMS - PRIMARY SURGERY
P090804010103	MODULAR CEMENTED FEMORAL STEMS - PRIMARY SURGERY
P090804010104	CEMENTED FEMORAL STEMS - PRIMARY SURGERY, CONSERVATIVE

Certificate bears the qualified signature.
Warsaw, 07.11.2025

POLISH CENTRE FOR
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Kod EMDN	Generic name by code:
P090903020103	CEMENTABLE MOBILE BEARING TIBIAL TRAYS - BICOMPARTIMENTAL PRIMARY KNEE REPLACEMENT
P090903020104	CEMENTED FIXED BEARING TIBIAL TRAYS - BICOMPARTIMENTAL PRIMARY KNEE REPLACEMENT
P090903020105	UNCEMENTED FIXED BEARING TIBIAL TRAYS - BICOMPARTIMENTAL PRIMARY KNEE REPLACEMENT
P090903020106	CEMENTABLE FIXED BEARING TIBIAL TRAYS - BICOMPARTIMENTAL PRIMARY KNEE REPLACEMENT
P090903020201	MOBILE BEARING TIBIAL INSERTS - BICOMPARTIMENTAL PRIMARY KNEE REPLACEMENT
P090903020202	FIXED BEARING TIBIAL INSERTS - BICOMPARTIMENTAL PRIMARY KNEE REPLACEMENT
P09090401	FEMORAL COMPONENTS - UNICOMPARTIMENTAL KNEE REPLACEMENT
P0909040201	TIBIAL TRAYS - UNICOMPARTIMENTAL KNEE REPLACEMENT
P0909040202	TIBIAL INSERTS - UNICOMPARTIMENTAL KNEE REPLACEMENT
P09090501	FEMORAL COMPONENTS - REVISION KNEE REPLACEMENT
P090905020101	MOBILE BEARING TIBIAL TRAYS - REVISION KNEE REPLACEMENT
P090905020102	FIXED BEARING TIBIAL TRAYS - REVISION KNEE REPLACEMENT
P090905020201	MOBILE BEARING TIBIAL INSERTS - REVISION KNEE REPLACEMENT
P090905020202	FIXED BEARING TIBIAL INSERTS - REVISION KNEE REPLACEMENT
P09099001	PATELLAR COMPONENTS
P09099002	STEM EXTENSIONS
P09099099	KNEE PROSTHESIS - OTHERS
P09120201	BONE FIXATION NAILS, INTRAMEDULLARY
P09120202	BONE FIXATION NAILS, INTRAMEDULLARY, COMPLEX SYSTEMS
P09120299	BONE FIXATION NAILS - OTHERS

Kod EMDN	Generic name by code:
P900206	SURGICAL MESHES, METALLIC
P900299	SURGICAL MESHES - OTHERS
P900403	NON-BIODEGRADABLE DEVICES, FILLER AND RECONSTRUCTIVE
P900404	SUPPORTS FOR AUTOLOGOUS GRAFTS
P9099	IMPLANTABLE PROSTHETIC DEVICES - OTHERS