3EC® international

SNAS Reg. No. 305/R-064

CERTIFICATE

This certifies that the Quality management system for medical devices of company

LASAK s.r.o.

Seat: Českobrodská 1047/46, Hloubětín, 190 00 Praha 9, Czech Republic

Site: Jiráskova 601, 295 01 Mnichovo Hradiště, Czech Republic

LASAK

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN AND DEVELOPMENT, PRODUCTION, SALES, DISTRIBUTION AND SERVICE OF NON-ACTIVE IMPLANTABLE MEDICAL DEVICES, COMPONENTS AND SUBASSEMBLIES.

DENTAL IMPLANT SYSTEMS INCLUDING ENDOSTEAL IMPLANTS, ABUTMENTS, CROWNS, BRIDGES, DENTAL KITS, OTHER ASSOCIATED PROSTHETIC AND IMPRESSION COMPONENTS, INSTRUMENTS AND ACCESSORIES (BioniQ, IMPLADENT).

CUSTOM-MADE DEVICES FOR USE IN ORAL AND MAXILLOFACIAL SURGERY AND IMPLANTOLOGY

SPINAL IMPLANTS AND ASSOCIATED INSTRUMENTS AND ACCESSORIES (IMPLASPIN).

SYNTHETIC RESORBABLE AND NON-RESORBABLE MATERIALS FOR BONE REGENERATION (PORESORB-TCP, OssaBase-HA).

CUSTOM-MADE MEDICAL DEVICES CRANIAL IMPLANTS (Cranio-Oss).

Certificate No.: M-0557/23 **Date of issuance: October 27th, 2023** **Original date of approval: October 27th, 2023**

This certificate is valid from **October 27th, 2023** to **October 26th, 2026** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.