



CERTIFICATE

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

ALFAMEDIC s.r.o.

třída 5. května 458/35, 373 72 Lišov, Czech Republic



*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, SALE AND SERVICE OF ACTIVE MEDICAL DEVICES
INTENDED FOR TREATING HYPOTHERMIC CONDITIONS OF PATIENTS,
PHOTOTHERAPY AND HEATING OF APPLICATION SOLUTIONS**

Certificate No.: M-0595/25


Date of issuance: June 3rd, 2025

Original date of approval: June 3rd, 2025

This certificate is valid from June 3rd, 2025 to June 2nd, 2028 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.