



CERTIFICATE

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

EMS Handels Gesellschaft m.b.H.

Jochingergasse 1, A-2100 Korneuburg, Austria



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

EN ISO 13485:2016

for the following scope:

RESEARCH, DESIGN, PRODUCTION, SALES AND SERVICE OF ELECTROPHYSIOLOGICAL DIAGNOSTIC SYSTEMS AND MONITORING SYSTEMS

Certificate No.: M-0346/18

Date of issuance: August 28th, 2018

Original date of approval: August 29th, 2003

This certificate is valid from August 28th, 2018 to May 10th, 2020 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.

This certificate fully supersedes previous certificate No. M-0346/17 issued on April 26th, 2017.

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



Dr. Katarína Tomín 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.