

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-558-135-2111

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.

as a Certification Body with ID No. NAH-4-0009/2021/K
accredited by the National Accreditation Authority for management system certification
certifies that the quality management system applied by

SONMEDICA, S.L.
Congost, 28
08024 Barcelona
Spain

meets the requirements of standard

EN ISO 13485:2016

in the field:

Design, manufacturing and sales of MEGOS SpO₂ sensors;
Manufacturing and sales of MEGOS oxygen cells;
Manufacturing of i-Cardio Electrocardiograph;
Repair of transducers for foetus monitoring and SpO₂ sensors;
Distribution, sales and repair
of diagnostic and therapy equipment and their accessories;
Distribution, sales and repair of vital sign monitors and their accessories
including NIBP, SpO₂, ECG and other parameters

Registry number of the related audit report: NE/1061/2021

This certificate is valid until **2024-11-20** supposed that the results of the regular yearly surveillance audits are satisfactory.

The Company has been certified since 2012-11-21.

Budapest, 2021-11-21


László Imre
Managing Director



EMKI 2791

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu

