

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-498-135-1811

The Directorate of Device Testing and Clinical Engineering (EMKI)

as a Certification Body with ID No. NAH-4-0096/2016
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: **43-1888-2012**

This certificate is valid until **2021-11-20** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

Budapest, 2018-11-21



Head of EMKI



EMKI 2130

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

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EMKI