

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-828-200-1711

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

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

for the products / product categories:

MEGOS SPO₂ Sensors
MEGOS Oxygen Cells

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **NE/1061/2020**

This certificate is valid until **2022-11-20** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 3

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 21 November 2017.

Budapest, 2020-08-14


László Imre
Managing Director



EMKI 2539

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.

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www.emki.hu

ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-828-200-1711

The certificate is valid for the following manufacturing site / facility:

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

The certificate is valid for the following models:

Product	Model	Classification	
Oxygen cells (sensors)	E-01, E-02, E-03, E-04, E-05, E-06, E-07, E-07ST, E-08, E-09, E-10, E-11, E-12, E-13, E-14, E-15, E-15TD, E-15M, E-16, E-16HT, E-18, E-25, E-43, E-47, E-48, E-80	Ila, rule 2	
SpO ₂ sensors	NF SERIES	Finger Clip Sensors	IIb, rule 10
	NY SERIES	Flexi-Site System Y	
	NR SERIES	Ear Sensors	
	NW-AN & NW-PI SERIES	Wrap Sensors	
	ND-A, ND-P, ND-I & ND-AN SERIES	Flat Disposable Sensors	
	NFP SERIES	Finger Clip Pediatric Sensors	
	NSN SERIES	Neonate-Adult Flexi-Site System Sensors	
	NSA SERIES	New Soft Adult Finger Sensors	
NSP SERIES	New Soft Pediatric Finger Sensors		

Issue: 3

Date: 2020-08-14

First issued: 2017-11-21


László Imre
Managing Director



EMKI

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