



EC Certificate

Full Quality Assurance System

Certificate No.:
10330-2017-CE-POL-NA-PS Rev. 0

Project No.:
PRJC-236953-2010-PRC-POL

Valid Until:
06 SEPTEMBER 2020

This is to certify that the quality system of:

SONOMED Sp. z o.o.

ul. Pruszkowska 4d
02-118 Warszawa
Poland

For design, production and final product inspection/testing of:

Ultrasonic Devices
Patient Monitors

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 16 May 2017



For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0	Replaces the Certificate 7387-2015-CE-POL-NA (NB 0434), following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460). Issued after scope extension (products in bold)	2017-05-16

Products covered by this Certificate:

Product Description	Product Name	Class
Ultrasonic Devices Patient Monitors	Ultrasonic Doppler UD48V	IIa
	Vascular Doppler VENO	IIa
	SONOMED Doppler Blood Flow Detector MD4, MD4-CW8	IIa
	Fetal Heartbeat Detector FEDO	IIa
	Ultrasonic transducers CW2, PW2, CW4, CPW4, CW5, CW8, CPW8, FCW8, SPW16	IIa
	Ultrasonic Doppler digiTDS	IIa
	Patient Monitor Model S1	IIb
	Ultrasound ACG (ACG - acoustocerebrography) Diagnostic Device - UltraEASY 2p	IIa

The complete list of devices is filed with the Notified Body



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Sites covered by this certificate

Site Name	Address	Site Scope
SONOMED Sp. z o.o.	ul. Pruszkowska 4d, 02-118 Warszawa, Poland	Ultrasonic Devices Patient Monitors

EU Representative

N/A

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate