EC CERTIFICATE

Number: 3900521CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class IIa, IIb or III)

Manufacturer:
Viasonix Ltd.
10 Hamelacha St.
Ra'anana 4366105
Israel

Digitally signed by Grosu Marina
Date: 2022.06.15 10:43:54 EEST
Reason: MoldSign Signature
Location: Moldova

For the product category(ies)

Medical systems using Doppler probes, PPG sensors, temperature sensor and pressure cuffs for peripheral, Extracranial, intracranial and intraoperative vascular diagnosis and monitoring

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 3900520CN, initially dated 24 February 2012
Addendum, initially dated 1 March 2012

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.
The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 February 2023
Issued for the first time: 1 March 2012
Revised: 15 May 2017
Reissued: 1 February 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 3900521CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical systems using Doppler probes, PPG sensors, temperature sensor and pressure cuffs for peripheral, Extracranial, intracranial and intraoperative vascular diagnosis and monitoring

Issued to:

Viasonix Ltd.
10 Hamelacha St.
Ra'anana 4366105
Israel

This certificate covers the following product(s):

- Falcon/Pro (Class IIa, using Doppler probes, PPG sensors, temperature sensor and pressure cuffs)
- Falcon/Quad (Class IIa, using Doppler probes, PPG sensors, temperature sensor and pressure cuffs)
- Falcon/ABI+ (Class IIa, using PPG sensors, temperature sensor and pressure cuffs)
- Dolphin/IQ (Class IIa, using Doppler probes)
- Dolphin/4D (Class IIa, using Doppler probes)
- Dolphin/Max (Class IIa, using Doppler probes)

Initial date: 1 March 2012
Revision date: 8 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
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