Dolphin EC Declaration of Conformity

We, **Viasonix Ltd.**, located in 10 Hamelacha St., Ra'anana, 4366105, Israel, manufacturers of vascular diagnostic devices, as detailed hereunder, that are placed in the European market, declare that our Dolphin products conform and meet the essential requirements set out in Annex V/VII of the Medical Device Directive 93/42 EEC (amended by MDD 2007/47/EC). This declaration is valid for all the products produced starting December 2016, where the last 2 digits in the serial number (SN) represent the year of manufacture (YY). We have appointed Dekra Certification B.V. (0344) to act as our notified body to audit us in accordance with Annex V/VII.

Products:	Starting SN	Part #:	Class:
Dolphin/IQ	**IQ00117**	**PVC0200**	**IIa**
Dolphin/4D	**4D00117**	**PVC0201**	**IIa**
Dolphin/MAX	**MAX00119**	**PVC0227**	**IIa**

All products with optional sensors, probes and accessories:
Wired and wireless Remote Control
Foot Switch
2 MHz PW Doppler probe
2 MHz PW Monitoring Doppler probe (up to 5 m cable)
4MHz PW/CW Doppler probe
8MHz PW/CW Doppler probe
1.6MHz PW Doppler probe
16MHz PW single use sterilized Doppler probe
Monitoring head set
Dolphin/XF robotic probe
External channel connection box
Stand for Dolphin/4D and Dolphin/MAX

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Date: 2022.06.15 10:40:31 EEST
Reason: MoldSign Signature
Location: Moldova

Conforming to Production Standards:
ISO 13485:2016

Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed Arazy Group GmbH, from the Squaire 12, Am Flughafen,,60549 Frankfurt am Main, Germany, E-mail: germany@arazygroup.com, to act as our Authorized Representative in the European Community.

Full Name: Dan Manor Position: CEO

Date: 12.2.20 Signature: _____