VASCOSCOPE

Declaration of Conformity

Manufacturer Name:	Vascoscope B.V.
Manufacturer Address:	Esther de Boer-van Rijklaan 45 NL-3584GL Utrecht The Netherlands
SRN (Single Registration Number):	NL-PR-000014671
Basic UDI:	87202996727/G1-PS-01/9Y
Name of the product(s):	Vascoscope Probe Stabilizer
Classification:	Class I according to rule 13

Vascoscope B.V. does hereby declare that the above mentioned product(s):

- Meet the relevant provisions of Regulation (EU) 2017/745
- Comply to the applicable general safety and performance requirements as defined in Annex I of the Medical Device Regulation (EU) 2017/745.
- Have technical documentation available in accordance with Annex II and Annex III of the Medical Device Regulation (EU) 2017/745.
- Are designed, manufactured and tested in accordance with the quality management system, which complies to EN ISO 13485:2016 and art. 10-9 of Regulation (EU) 2017/745, of Vascoscope B.V.

Applied standards:

Reference	**Title**
ISO 14971:2019	Medical devices- Risk management
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General Requirements
ISO-20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices

This declaration of conformity is issued under the sole responsibility of Vascoscope B.V.

Utrecht, February 15, 2022

Huibert Tjabbes, CEO