Statement of Conformity with art 22 MDR

Manufacturer Name:	Vascoscope B.V.
Manufacturer Address:	Esther de Boer-van Rijklaan 45 NL-3584GL Utrecht The Netherlands
SRN (Single Registration Number):	NL-PR-000014673
Basic UDI:	87202996727G1-SY-01T2
Name of the system:	Vascoscope System
Consisting of:	1. Telemed Ultrasound scanner consisting of MicrUs beamformer with Telemed L12-5N40-MV3 and Telemed EchoWave II software [R1] 2. Microsoft Surface Pro 7 [R2] 3. Vascoscope Probe Stabilizer [R3] 4. Capsa Slimcart [R4], [R6] 5. Optional: Cedexis video glasses Jena [R5]

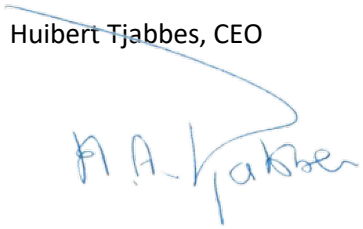
Vascoscope B.V. does hereby declare that the above mentioned system:

- Complies to the requirements set in article 22 of the Medical Device Regulation (EU) 2017/745
    - Mutual compatibility of the devices is verified in accordance with the manufacturers' instructions and the verification activities carried out are in accordance with those instructions;
    - The system and all relevant information to users that is supplied by the manufacturers of the devices and other products is incorporated in the information supplied to the user;
    - The activity of combining devices and other products as a system was subject to appropriate methods of internal monitoring, verification and validation;
- Compiled and delivered in accordance with the Vascoscope QMS system, which complies to ISO 13485.

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

Utrecht, February 17, 2022

Huibert Tjabbes, CEO



Reference documents

[R1] G1-US-EXT-01 MicrUs_DoC_2021
[R2] G1-TB-EXT-01 DoC_Surface pro 7 m1866
[R3] G1-PS-DOC-01 Declaration of conformity
[R4] G1-CA-EXT-02 DoC CE_RoHS SlimCart,
[R5] VH-VG-EXT-01 Cedexis Jena declaration of Conformity
[R6] G1-CA-EXT-03 Declaration of Compliance 60601