EU DECLARATION OF CONFORMITY

The following EU declaration of conformity exemplifies the required content according to Regulation (EU) 2017/745.

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:	SONOSCAPE MEDICAL CORP. Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Subdistrict, Nanshan District, Shenzhen, 518057, Guangdong, China
Single registration number (SRN)	CN-MF-000009623
Name and address of the European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Single registration number (SRN)	DE-AR-000000001

We declare under our sole responsibility that

the medical device:	Digital Color Doppler Ultrasound System Model No.: P60 Exp, P60, P60 Pro, P60 CV, P70T, P70S, P60S, P60 VO, P55, P55 Elite, P55S, P50T, P50 Elite, P50E, P40T, P40 Elite, P40E, P30T, P30 Elite, P30E, P25S, P22S, SonoStage M1
of class:	IIa according to annex VIII Rule 10 of Regulation (EU) 2017/745
Basic UDI-DI	69458686U1001S9 (P60 Exp) 69458686U1002SB (P60, P60 Pro, P60 CV, P70T, P70S, P60S, P60 VO, P55, P55 Elite, P55S, P50T, P50 Elite, P50E, P40T, P40 Elite, P40E, P30T, P30 Elite, P30E, P25S, P22S, SonoStage M1)
EMDN Code:	Z110401

meets the provisions of the Regulation (EU) 2017/745. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure:	**Regulation (EU) 2017/745 Annex IX Chapters I and III**
Registration No.:	**HZ 2027206-1**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, 2023-08-21 — Zhou Wenping, Vice President

Place, date — Name and function