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.: S12 Exp, S12 Pro, S12, S11 Plus, M12, S10, S11s, S12s
of class:	IIa
	according to annex VIII of Regulation (EU) 2017/745
Basic UDI-DI	69458686U1005SH(S12 Exp, S12 Pro, S12, S11 Plus, M12, S10, S11s, S12s)
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, Aug. 21, 2023 — Zhou Wenping Vice President

Place, date — Name and function