EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2027206-1

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
P.R. China

EUDAMED Single Registration No.: CN-MF-000009623

Products: Products of Class IIa:
Z110401 – ULTRASOUND SCANNERS
Z110402 – ULTRASOUND PROBES
Z120204 – INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Z120205 – UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Z120206 – LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Z120290 – VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY

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Authorised representative(s): Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-10-14

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 10918951-130

Effective date: 2022-10-14

Expiry date: 2027-07-29

Issue date: 2022-10-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TUVRheinland®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.