EU Certificate

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

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 Z120208 – PULMONARY ENDOSCOPIC INSTRUMENTS Z120207 – GENITOURINARY ENDOSCOPY INSTRUMENTS Z120210 – ENT ENDOSCOPY INSTRUMENTS

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.:	10922803-120
Effective date:	2024-10-31
Expiry date:	2027-07-29
Issue date:	2024-10-31

Samuel Qin
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

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

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

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EU Certificate

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

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 of class IIb: Z120290 – ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY INSTRUMENTS VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Authorized representative(s):	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2022-10-14
1	Scope extension	2023-07-21
2	Scope extension	2023-10-31
3	Scope extension	2024-01-30
4	Scope extension	2024-10-31

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