

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.: 10924069-100

Effective date: 2024-01-30

Expiry date: 2027-07-29

Issue date: 2024-01-30

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

Frank Feng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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bei Arzneimitteln und
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Annex IX Chapter I, Section 2 and 3 and Chapter III

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EUDAMED Single Registration No.: CN-MF-000009623

Authorized 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
1	Scope extension	2023-07-21
2	Scope extension	2023-10-31
3	Scope extension	2024-01-30

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