

EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

EC 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

Name and address of the European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

We declare under our sole responsibility that

the medical device: HD-550 Video Endoscope System including
(Product Name)

Video Gastroscope: (model No. EG-550, EG-550L)
Video Colonoscope: (model No. EC-550, EC-550T, EC-550L, EC-550L/T)
Image Processor: (model No. HD-550Exp, HD-550, HD-550Pro, HD-550S, HD-510, HD-500Plus)
Light Source: (model No. VLS-50T/VLS-50D, VLS-55Q/VLS-55T/VLS-51T/VLS-51D)
(Model Designation)

of class: IIa

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex II, excluding Section 4**

Registration No.: **HD 2027206-1**

Notified Body: **TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197**

Shenzhen, April 17, 2021

Place, date

Zhou Wenping
Vice President

Name and function