# DNV BUSINESS ASSURANCE

## EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 54317-2009-CE-RGC-NA 11.0
This Certificate consists of 4 pages

*This is to certify that the Quality Management System of*

**SonoScape Company Limited**

P. R. China

*for design, production and final product inspection/testing of*

Ultrasonic Diagnostic Systems

*has been assessed with respect to*
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

*Further details are given overleaf*

*Place and date:*
Høvik, 01 July 2014

*For* DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Cecilie Gudesen Torp
*Certification Manager*

NORWEGIAN ACCREDITATION
PROD 002

Notified Body No.:
0434

*This Certificate is valid until:*
02 July 2019

Dennis Lin
*Technical Reviewer*

*This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info*

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

## Certificate history

| Revision | Description | Issue Date |
|---|---|---|
| 1 | Original certificate | 2004-07-02 |
| 2 | Recertification | 2009-07-02 |
| 3 | Extension of Scope – New product added | 2010-03-19 |
| 4 | Extension of Scope- New product added | 2010-07-08 |
| 5 | Change of model name for one device | 2011-05-20 |
| 6 | Extension of Scope – New product added | 2011-11-09 |
| 7 | Extension of Scope – New product added | 2012-06-05 |
| 8 | Extension of Scope – New product added | 2012-09-06 |
| 9 | Extension of Scope – New product added | 2013-01-04 |
| 10 | Extension of Scope – New product added | 2013-08-15 |
| 11 | **Recertification** | **2014-07-02** |

## Products covered by this Certificate

| Product Description | Product | Class |
|---|---|---|
| Digital Color Doppler ultrasound System | SSI-5000, SSI-4000, SSI-2000, SSI-1500 | IIa |
| Digital Color Doppler ultrasound System | SSI-6000, SSI-5800, SSI-5500, SSI-5500BW | IIa |
| Digital Color Doppler ultrasound System | S20 Exp, S20 Pro, S20, S15 | IIa |
| Portable Digital Color Doppler ultrasound System | S8, S8 Pro, S6 Pro, S6**,** S6BW | IIa |
| Mobile Digital Color Doppler ultrasound System | SSI-8000 Exp, SSI-8000 Pro, SSI-8000, SSI-8000 PE | IIa |
| Portable Ultrasonic Diagnostic System | A6T, A6, A5 | IIa |
| Mobile Ultrasonic Diagnostic System | A8T, A8, A7 | IIa |
| Digital Color Doppler ultrasound System | S11 Exp, S11 Pro, S11, S11 N, S11 BW | IIa |
| Digital Color Doppler ultrasound System | S40 Exp, S40 Pro, S40, S35 | IIa |
| Digital Color Doppler ultrasound System | SSI-5000N, SSI-4000N, SSI-3000N, SSI-2000N, SSI-1500N | IIa |
| Portable Digital Color Doppler ultrasound | S8N, S6N, S2N, S2, S2BW | IIa |

| | | |
|---|---|---|
| System | | |
| Portable Digital Color Doppler ultrasound System | S9 Exp, S9 Pro, S9, S8 Exp, S7, SSI-980 | IIa |
| Digital Color Doppler ultrasound System | S30 Exp, S30 Pro, S30, S25 | IIa |
| Digital Color Doppler ultrasound System | S12 Exp, S12 Pro, S12, S11 Plus, M12 | IIa |
| Digital Color Doppler ultrasound System | S22 Exp, S22 Pro, S22, S20N, M22 | IIa |

The complete list of devices is filed with the Notified Body.

**Sites covered by this certificate**

| Site Name | Address |
|---|---|
| SonoScape Company Limited | Yizhe Building, Yuquan Road, Nanshan, Shenzhen 518051, P. R. China |

**EU Representative**

SONOMED, Via Luigino Tandura, 74-00128 Rome, Italy

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE