ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 08 98976 001

Holder of Certificate: **Healson Technology Co., Ltd.**
Room #2001, 20th Floor
No.1858 Yizhou Avenue Middle
High-Tech Zone
610041 Chengdu, Sichuan Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Healson Technology Co., Ltd.
Room #2001, 20th Floor, No.1858 Yizhou Avenue Middle, High-Tech Zone, 610041 Chengdu, Sichuan Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Digitally signed by Grosu Marina
Date: 2020.10.08 09:33:35 EEST
Reason: MoldSign Signature
Location: Moldova

Scope of Certificate: **Design and Development, Production and Distribution of Digital Handheld Probe-type Ultrasound System**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH17117301

Valid from: 2017-12-20
Valid until: 2020-12-19

Date, 2017-12-20

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Page 1 of 1

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DAkkS CRT2 / A4 07.17 ZM

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 08 98976 002

Manufacturer:

Healson Technology Co., Ltd.
Room #2001, 20th Floor
No.1858 Yizhou Avenue Middle
High-Tech Zone
610041 Chengdu, Sichuan Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Prolinx GmbH
Brehmstr. 56
40239 Duesseldorf
GERMANY

Product Category(ies):

Digital Handheld Probe-type Ultrasound System

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH17117301

Valid from: 2017-12-20
Valid until: 2022-12-19

Date, 2017-12-20

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 08 98976 002

Facility(ies):

Healson Technology Co., Ltd.
Room #2001, 20th Floor, No.1858 Yizhou Avenue Middle, High-Tech Zone, 610041 Chengdu, Sichuan Province, PEOPLE'S REPUBLIC OF CHINA

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