



## Certificate

No. Q5 074840 0011 Rev. 01

Holder of Certificate: Shanghai Handy Medical

Equipment Co., Ltd.

Floor 2, Building No. 11, Lane 177, Fulian Er Road

Baoshan District 201906 Shanghai

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shanghai Handy Medical Equipment Co., Ltd.

Floor 2, Building No. 11, Lane 177, Fulian Er Road, Baoshan District, 201906 Shanghai, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 



Scope of Certificate: Design and Development,

Production and Distribution of Digital Dental X-ray Imaging System and Intraoral Camera and Digital

Imaging Plate Scanner

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.:

SH1964610

Valid from:

2020-02-16

Valid until:

2023-02-15

Date,

2020-01-13

Christoph Dicks

Head of Certification/Notified Body