



## **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 002987 0002 Rev. 00

Manufacturer: Northern Meditec Limited

4th Floor, Building C

Jin Wei Yuan Industrial Park Julongshan Area, Kengzi St

Pingshan District 518118 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Multi-parameter Patient Monitor, Anaesthesia

Machine, Ventilator

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.: GZ1910901

 Valid from:
 2020-02-28

 Valid until:
 2024-01-27

Date, 2020-02-28

Christoph Dicks

Head of Certification/Notified Body







## Certificate

No. Q5 002987 0001 Rev. 01

**Holder of Certificate: Northern Meditec Limited** 

4th Floor, Building C

Jin Wei Yuan Industrial Park Julongshan Area, Kengzi St

Pingshan District 518118 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Northern Meditec Limited

4th Floor, Building C, Jin Wei Yuan Industrial Park, Julongshan Area, Kengzi St, Pingshan District, 518118 Shenzhen, PEOPLE'S

REPUBLIC OF CHINA

**Certification Mark:** 



**Scope of Certificate:** Design and Development, Production and

Distribution of Multi-Parameter Patient Monitors,

Ventilators and Anaesthesia Machines

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.: GZ1910901

Valid from: 2020-01-28 Valid until: 2023-01-27

Date, 2020-01-20 Christoph Dicks

Head of Certification/Notified Body

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