



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 004665 0002 Rev. 00

Manufacturer:

Shenzhen Finicare Co., Ltd

201, Dehe Building
No. 81, Haoyong No.2 Industrial Park
Hongxing Community, Songgang Street
Bao'an District
518103 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Finicare Co., Ltd
201, Dehe Building, No. 81, Haoyong No.2 Industrial Park,
Hongxing Community, Songgang Street, Bao'an District, 518103
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product

Infrared Thermometer

Category(ies):

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

Report No.:

GZ1836501

Valid from:

2019-05-08

Valid until:

2024-05-07

Date,

2019-05-08

Stefan Preiß



Product Service

Certificate

No. Q6 004665 0001 Rev. 00

Holder of Certificate: **Shenzhen Finicare Co., Ltd**

201, Dehe Building
No. 81, Haoyong No.2 Industrial Park
Hongxing Community, Songgang Street
Bao'an District
518103 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Finicare Co., Ltd
201, Dehe Building, No. 81, Haoyong No.2 Industrial Park,
Hongxing Community, Songgang Street, Bao'an District, 518103
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of Infrared Thermometer**

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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1836501

Valid from: 2019-05-08

Valid until: 2022-05-07

Date, 2019-05-08

Stefan Preiß