

DAKKS CRT2 / 10.13



CERTIFICATE

No. Q1N 17 12 02231 001

Shenzhen Greatmade Tech limited Holder of Certificate:

3rd Floor, Building B

Baifuli Industrial Zone, Shanghenglang

Huahui Road, Dalang Street Longhua New District

518109 Shenzhen, Guangdong Province PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Greatmade Tech limited

3rd Floor, Building B, Baifuli Industrial Zone, Shanghenglang, Huahui Road, Dalang Street, Longhua New District, 518109 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF

CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production

and Distribution of Spo2 sensor,

Patient cable and leadwire, Blood pressure cuff

Applied Standard(s):

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -

Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)

DIN EN ISO 13485:2012

Upgrade required until 2019-03-31

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.:

GZ1728501

Valid from:

2018-04-11

Valid until:

2021-04-10

2018-04-11 Date.

Stefan Preiß

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