CF001A	Neonate Single tube NIBP cuff , 6-11cm Arm Circumference , L*W= 230*55mm , Bladder L*W=90*40mm
CF002A	Infant single tube NIBP cuff , 10-19cm Arm Circumference, L*W=330*85mm , Bladder L*W=130*72mm
CF003A	Child single tube NIBP cuff, 18-26cm Arm Circumference, L*W=410*115mm, Bladder L*W=175*75mm
CF004A	Adult single tube NIBP cuff , 25-35cm Arm Circumference ,L*W=510*140mm , Bladder L*W=230*118mm
CF004LA	Large Adult Single Tube Nibp Cuff, 33-47cm Arm Circumference, L*W=630*175mm, Bladder L*W=320*160mm
CF004TA	THIGH Single Tube Nibp Cuff, 46-66cm Arm Circumference.L*W=780*215mm,Bladder L*W=380*195mm



第 1 页



Product Service

## ficate

ance System

edical Devices (MDD), Annex II excluding (4)

31 002

## 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

## Prolinx GmbH

Brehmstr. 56 40239 Duesseldorf GERMANY

Spo2 sensor

DV SUD Product Service GmbH declares that the aforementioned nted a quality assurance system for design, manufacture and final devices / device categories in accordance with MDD Annex II. em conforms to the requirements of this Directive and is subject to marketing of class III devices an additional Annex II (4) certificate

GZ1728501

2018-04-11 2023-04-10



GmbH is Notified Body with identification no. 0123

mbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany



**EC** Certificate

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**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 12 02231 002

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 CERTIFICATE No. Q1N 17 12 02231 001 Holder of Certificate: Shenzhen Greatma

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3rd Floor, Building B Baifuli Industrial Zone, Shan Huahui Road, Dalang Street

> Longhua New District 518109 Shenzhen, Guangdo PEOPLE'S REPUBLIC OF C

Facility(ies):

Shenzhen Greatmade Tech 3rd Floor, Building B, Baifuli Shanghenglang, Huahui Roa Longhua New District, 51810 Guangdong Province, PEOF

Certification Mark:



Scope of Certificate:

Design and Developm and Distribution of Sp

Patient cable and lead

Applied Standard(s):

EN ISO 13485:2012 + AC:20 Medical devices - Quality ma Requirements for regulatory (ISO 13485:2003 + Cor. 1:2

DIN EN ISO 13485:2012 Upgrade required until 2019

The Certification Body of TÜV SÜD Product Service GmbH cer above has established and is maintaining a quality management requirements of the listed standard(s). See also notes overleaf.

Report No.:

GZ1728501

Valid from: Valid until:

2018-04-11

2021-04-10

Date, 2018-04-11

Page 1 of 1

TÜV SÜD Product Service GmbH · Zertifizierstelle - Ridlerstraße 65 · 80339 München · Germany

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TÜV SÜD Product Service GmbH + Zertifizierstelle - Ridlerstraße 65