

Suction Electrode

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)
		EC013A	Adult Suction Electrodes (6 pcs/Set) , perfect for 3.0 DIN , Silicone
		EC013B	Adult Suction Electrodes (6 pcs/ Set) , perfect for 4.0 Banana ,silicone
		EC013A/B	Adult Suction electrodes (6 pcs/ set) , for both 3.0 and 4.0, silicone
		EC013C	Adult Multi use electrode , 3.0, 4.0 ,Snap , grabber ,Metal PLATING AgCl (Dark)
		EC013C-S	Adult multi use electrode,3.0,4.0,Snap,grabber,Metal PLATING Nickel(Shine)
		EC013D	Pediatric Suction Electrode (6pcs/set) . suitable for 3.0 DIN plug
		EC013E	Pediatric Suction Electrode (6pcs/set) . suitable for 4.0 banana
		EC013F	Pediatric Multi-use Electrode(6 pcs/set),for 3.0 , 4.0 , Snap , Grabber ,Plating AgCl(Dark)
		EC013F-S	Pediatric Multi-use Electrode(6 pcs/set),for 3.0,4.0,Snap,Grabber,plating Nickel(Shine)
		EC013G	Pediatric suction Electordes (6pcs/set) , suitable for both 3.0 and 4.0

EC013C



EC013A Suitable for all 3.0mm DIN plug for EKG cable

EC013B Suitable for All 4.0 Banana Plug of EKG Cable .

EC013C For Multi-use , Suitable for all 3.0DIN , 4.0 Banana , Snap and Grabber

EC013A/B is suitable for both 3.0 and 4.0 banana plug

EC013A/B: Metal diameter : 21mm ,Ball diameter :26mm

EC013C Metal diameter : 24mm , Ball diameter : 32mm

EC013D/E Metal diameter :17mm, Ball diameter :23mm





Product Service

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 17 12 02231 002

Manufacturer: 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



EC-Representative: Prolinx GmbH

Brehmstr. 56
40239 Duesseldorf
GERMANY

Product Category(ies): Spo2 sensor

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.: GZ1728501

Valid from: 2018-04-11
Valid until: 2023-04-10



Date, 2018-04-11

S. Preis
Stefan Preis

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

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 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
CHINA

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Product Service

CERTIFICATE

No. Q1N 17 12 02231 001

Holder of Certificate: 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

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

Date, 2018-04-11

S. Preis
Stefan Preis



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