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Limb Electrode					
OEM P/N	Greatmade No.		1-5 sets	6-19 sets	1-5 sets 6-19 sets Above 20sets
	EC012	Limb Electrode (4pcs/set) Perfect for 3.0 plug. IEC (RED , Yellow , Green , Black)			
	EC012B	Limb Electrode (4pcs/set) Perfect for 4.0 Banana, IEC ,(RED , Yellow , Green , Black)			
	EC012C	Multi-use Limb Electrode for all types of ECG electrode, Metal plating AgCI (Dark), IEC			
	EC012C-S	${ m EC012C-S}$ Multi-use Limb Electrode for all types of ECG electrode , Metal plating Nickel (Shine), IEC			
	EC012-A	${ m EC012-A}$ Limb Electrode (4pcs/set) Perfect for <u>3.0 D/N</u> .AHA,(RED,Green,White,Black)			
	EC012B/A	${ m EC012B/A}$ Limb Electrode (4pcs/set) Perfect for <u>4.0 Banana</u> ,AHA,(RED,Green,White,Black)			
	EC012C/A	${ m EC012C/A}$ Multi-use Limb Electrode for all types of ECG electrode , Metal plating AgCI (Dark), AHA			
	EC012C-SA	${ m EC012C ext{-}SA}$ Multi-use Limb Electrode for all types of ECG electrode , Metal plating Nickel (Shine), AHA			









EC012A Suitable for all 3.0 Din Plug of EKG Cable EC012B Suitable for All 4.0 Banana Plug of EKG Cable. EC012C Suitable for All 4.0 Banana, 3.0DIN, Snap, Grabber electrode

Limb Electrode

בווווט בונכנו סמכ					
OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	6-19pcs Above 20pcs
	EC012A-HP	$ m EC012A ext{-}HP$ Limb Electrode (4pcs/set) Perfect for $3.0D$ I/V ,IEC,(Red,Green,Yellow,Black)			
	EC012B-HP	${ m EC012B ext{-}HP}$ Limb Electrode (4pcs/set) Perfect for <u>4.0 Banana</u> JEC,(Red,Green,Yellow,Black)			
	EC012C-HP	$ { m EC012C-HP} $ Multi-use Limb Electrode for all types of ECG electrode,Metal plating AgCI (Dark), IEC			
	EC012D-HP	EC012D-HP Multi-use Limb Electrode for all type當句 與G 爾 ectrode. Metalf plating Nickel(Shine),IEC			

EC012E-HP Limb Electrode (limb Electrode(4pcs/set)Perfect for <u>3.0 D//N</u> ,AHA,(Red,Green,White,Black)		
$ ext{EC}012 ext{F-HP} $ Limb Electrode (.imb Electrode (4pcs/set) Perfect for <u>4.0 Banana</u> ,AHA,((Red,Green,White,Black))		
EC012G-HP Multi-use Limb El	Multi-use Limb Electrode for all types of ECG electrode, Metal plating AgCI (Dark), AHA		
EC012H-HP Multi-use Limb E	Multi-use Limb Electrode for all types of ECG electrode, Metal plating Nickel(Shine),AHA		









OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
	EC012E	Limb Electrode (4pcs/set) Perfect for 3.0 DIN (Red , Green , Yellow , Black)			
	EC012F	Limb Electrode(4bcs/set)Perfect for 4.0 Banana ((Red . Green . Yellow . Black)			



	No. Desceiption (Cable and connector)	Pediatric Multi-use Limb Electrode with Screw, Plastic clamp Between upper and lower shells	${ m EC012D}$ -B $~$ Pediatric Multi-use Limb electrode with Screw,Metal Clamp between upper and lower shell	ECOLZD -B
atile Ellin Elections	Greatmade No.	EC012D	EC012D-F	19.

OEM P/N



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Suction Electrode

OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	6-19pcs Above 20pcs
	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	${ m EC013}A/{ m B}$ 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 AgCI (Dark)			
	EC013C-S	${ m EC013C ext{}S}$ 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	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			



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 forboth 3.0 and 4.0 banana plug

FC013A/B: Metal diameter : 21mm ,Ball diameter :26mm

C013C Metal diameter : 24mm, Ball diameter : 32mm

C013D/E Metal diameter :17mm, Ball diameter :23mm

EC013D



EKG Cable Electrode Adapter

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OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	1-5pcs 6-19pcs Above 20pcs
	EC018A	Electrode Adapter , 3.0DIN-> Snap , L=10CM			
	EC018B	Electrode Adapter , 4.0 Banana -> Snap , L=10CM			
	EC018C	Electrode Adapter , 3.0DIN->Grabber, L=10CM			
	EC018D	Electrode Adapter , 4.0 Banana-> Grabber , L=10CM			
	$ \text{EC018}\overline{\text{E}} $	Eelectrode Adapter , 4.0 Banana socket -> 3.0 DIN Plug, L=10CM			
	EC018E	Polosto de Adonte o One Marie Carlos de Adonte			





CERTIFICAT

CERTIFICADO

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CERTIFICATE

ZERTIFIKAT

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

Prolinx GmbH EC-Representative:

> Brehmstr. 56 40239 Duesseldorf GERMANY

Product Spo2 sensor Category(ies):

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 Stefan Preiß

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

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

TUV®



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

CERTIFICAT CERTIFICADO • СЕРТИФИКАТ .

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CERTIFICATE

ZERTIFIKAT

CERTIFICATE

Holder of Certificate: Shenzhen Greatmade Tech limited

3rd Floor, Building B

Longhua New District

Baifuli Industrial Zone, Shanghenglang Huahui Road, Dalang Street

518109 Shenzhen, Guangdong Province

3rd Floor, Building B, Baifuli Industrial Zone,

Longhua New District, 518109 Shenzhen Guangdong Province, PEOPLE'S REPUBLIC OF

Shanghenglang, Huahui Road, Dalang Street,

PEOPLE'S REPUBLIC OF CHINA

Shenzhen Greatmade Tech limited

No. Q1N 17 12 02231 001

Scope of Certificate: Design and Development, Production

and Distribution of Spo2 sensor,

Patient cable and leadwire, Blood pressure cuff

Applied

Facility(ies):

Certification Mark:

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -Standard(s):

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:

Valid until: 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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