



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****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:**

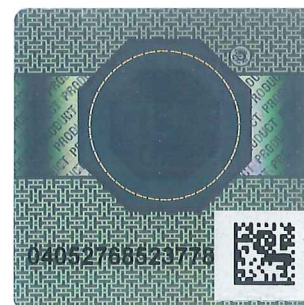
2018-04-11

**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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**Facility(ies):**

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