A4 / 07.17







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 065652 0010 Rev. 00

Manufacturer:

Shenzhen Launch Electrical Co., Ltd.

Building F Zhonggangxing Industrial Estate Zhangge Community, Guanlan Street Longhua New District 518110 Shenzhen PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Launch Electrical Co., Ltd. Building F, Zhonggangxing Industrial Estate, Zhangge Community, Guanlan Street, Longhua New District, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): SpO2 Sensor, Temperature Probe

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.:

GZ18129EXT01

Valid from: Valid until: 2018-08-07 2023-05-02

Date, 2018-08-07

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Stefan Preiß