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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 087056 0005 Rev. 02

Manufacturer:

Shanghai Berry Electronic Tech Co., Ltd.
Unit 104, 1st Floor, 7th Building
No. 1188 Lianhang Road
Minhang District
201112 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf, GERMANY

Product Category(ies): **Pulse Oximeter, Spo2 Sensor, Patient Monitor**

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.: SH19810EXT01

Valid from: 2019-05-16
Valid until: 2024-05-15

Date, 2019-03-08

Stefan Preiß

Digitally signed by Granaci Boris
Date: 2020.05.14 10:16:01 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

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Facility(ies):

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Unit 104, 1st Floor, 7th Building, No. 1188 Lianhang Road,
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