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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

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 098084 0003 Rev. 01

Manufacturer:

Orantech Inc.
Zone#A, 4F
1st Bld, 7th Industrial Zone
Yulv Community, GongMing
Guangming New District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Spo2 Sensor, Temperature Probe, Fetal transducer and ETCO2 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.: GZ1928002

Valid from: 2020-01-10
Valid until: 2024-05-26

Date, 2020-01-10

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Cojocaru Vera
Date: 2020.11.23 08:44:29 EET
Reason: MoldSign Signature
Location: Moldova

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

Orantech Inc.
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community,
GongMing, Guangming New District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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