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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 093032 0005 Rev. 00

Manufacturer:

Xuzhou Maicuff Technology Co.,Ltd.

8#-2-1106 Jinxiujiayuan, Jianguo West Road

221006 Xuzhou City, Jiangsu Province

PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Xuzhou Maicuff Technology Co.,Ltd.

8#-2-1106 Jinxiujiayuan, Jianguo West Road, 221006 Xuzhou

City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Xuzhou Maicuff Technology Co., Ltd.

3rd Floor, D Building, No.47 Zhujiang Road, Tongshan District,

221116 Xuzhou City, Jiangsu Province, PEOPLE'S REPUBLIC

OF CHINA

Product Category(ies): Spo2 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.:

SH19875EXT01

Valid from:

2020-01-20

Valid until:

2024-05-26

Date,

2020-01-20

Christoph Dicks

Head of Certification/Notified Body