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

TÜV SÜD 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 093129 0005 Rev. 02

Manufacturer:

Suzhou MicroPort Spine & Trauma Co., Ltd.
Area B, Building #2
No.112, Fangzhong Street
Suzhou Industrial Park
215000 Suzhou Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Fusion Device,
Orthopedic Bone Screw,
Anterior Cervical Plate System,
Spinal Posterior Fixation System,
Locking Compression Plate System

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.: SH19929CN01

Valid from: 2019-09-05

Valid until: 2024-05-26

Date, 2019-09-05

Stefan Preiß
Head of Certification/Notified Body

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):

Suzhou MicroPort Spine & Trauma Co., Ltd.
Area B, Building #2, No.112, Fangzhong Street, Suzhou Industrial Park, 215000 Suzhou Jiangsu, PEOPLE'S REPUBLIC OF CHINA

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