CERTIFICATE

Number: 6053560

The management system of:

Suzhou GEMMED Medical Instrument Co., Ltd.

A22 & 26 Science & Technology Development Zone, Jinnan Road, Jinfeng Town
215625 Zhangjiagang City, Jiangsu
China

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:
Design and Development, Manufacture and Distribution of Metallic Bone Plates & Screws Systems, Internal Spinal Fixation Systems, Spinal Fusion Cages, Intramedullary Nails, Orthopedic Fixation Nails, External Fixation Systems

Certificate expiry date: 1 November 2022
Certificate effective date: 17 November 2019
Certified since: 17 November 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

Digitally signed by Iarovoi Petru
Date: 2022.03.18 09:52:47 EET
Reason: MoldSign Signature
Location: Moldova

MGMT. SYS. RvA C 589

ADDENDUM

Belonging to certificate: 6053559CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Non-active orthopaedic devices

Issued to:

Suzhou GEMMED Medical Instrument Co., Ltd.
A22 & 26 Science & Technology Development Zone, Jinnan Road, Jinfeng Town
215625 Zhangjiagang City, Jiangsu
China

This certificate covers the following product(s):

- Metallic Bone Plates & Screws Systems
- Internal Spinal Fixation Systems
- Spinal Fusion Cages
- Intramedullary Nails
- Orthopedic Fixation Nails
- External Fixation Systems

Initial date: 18 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC CERTIFICATE

Number: 6053559CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:
Suzhou GEMMED Medical Instrument Co., Ltd.
A22 & 26 Science & Technology Development Zone, Jinnan Road, Jinfeng Town
215625 Zhangjiagang City, Jiangsu
China

For the product category(ies)

Non-active orthopaedic devices

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 6053559CN, initially dated 18 July 2019
Addendum, initially dated 18 July 2019

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 21 October 2021
Issued for the first time: 18 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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