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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 065765 0033 Rev. 00

Manufacturer:

Foosin Medical Supplies Inc., Ltd.
No.8-1, Weigao West Road
Chucun Town, Torch Hi-Tech Science Park
264200 Weihai, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000006957

Authorized Representative:

MedNet EC-REP C III GmbH
Borkstrasse 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 065765 0033 Rev. 00

Report No.: 713217562

Valid from: 2024-05-08
Valid until: 2029-05-07

Issue date: 2024-05-08

Christoph Dicks
Head of Certification/Notified Body

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No. G70 065765 0033 Rev. 00

Classification:	Class III
Device Group:	H010101 - ABSORBABLE SYNTHETIC SUTURES
Basic UDI-DI:	69418136AB-suturesIIIGBPY
Intended Purpose:	WEGO-PGA suture is an absorbable suture indicated for general soft tissue approximation and/or ligation.
Device(s):	Synthetic Absorbable Suture(WEGO-PGA): Sterile, braided synthetic absorbable surgical suture with the following parameters: Suture sizes (diameters): EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6 USP: 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3 Suture Lengths: max. 390cm Color: Violet; Natural White Article codes see list “Appendix ABC“ dated 2024-05-06

Classification:	Class III
Device Group:	H010101 - ABSORBABLE SYNTHETIC SUTURES
Basic UDI-DI:	69418136AB-suturesIIIGMQN
Intended Purpose:	WEGO-PGA suture is an absorbable suture indicated for general soft tissue approximation and/or ligation.
Device(s):	Synthetic Absorbable Suture(WEGO-PGA): Sterile, monofilament synthetic absorbable surgical suture with the following parameters: Suture sizes (diameters): EP: 0.2, 0.3 USP: 10-0, 9-0 Suture Lengths: max. 75cm Color: Violet; Natural White Article codes see list “Appendix ABC“ dated 2024-05-06

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The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report	Description
00	2024-05-08	713217562	Initial issuance

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