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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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TÜV SÜD
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

| | |
|---|---|
| **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):<br><br>Sterile, braided synthetic absorbable surgical suture with the following parameters:<br><br>Suture sizes (diameters):<br>EP: 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6<br>USP:<br>8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3<br>Suture Lengths: max. 390cm<br>Color: Violet; Natural White<br><br>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):<br><br>Sterile, monofilament synthetic absorbable surgical suture with the following parameters:<br><br>Suture sizes (diameters):<br>EP: 0.2, 0.3<br>USP: 10-0, 9-0<br>Suture Lengths: max. 75cm<br>Color: Violet; Natural White<br><br>Article codes see list “Appendix ABC“ dated 2024-05-06 |

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# 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

**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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# EU Quality Management System Certificate (MDR)

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

## No. G12 065765 0025 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 established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G12 065765 0025 Rev. 00

**Report No.:** BJ24092601

**Valid from:** 2024-05-15
**Valid until:** 2029-05-14

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2024-05-15


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# EU Quality Management System Certificate (MDR)

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

## No. G12 065765 0025 Rev. 00

| | |
|---|---|
| **Classification:** | Class III |
| **Device Group:** | H010101 - ABSORBABLE SYNTHETIC SUTURES |
| **Intended Purpose:** | - |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | - none - |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-05-15 | BJ24092601 | Initial issuance |



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# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 065765 0031 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 established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 065765 0031 Rev. 00

**Report No.:** BJ20092603

**Valid from:** 2024-02-19
**Valid until:** 2029-02-18

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2024-02-19


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# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 065765 0031 Rev. 00

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | H010201 - NON-ABSORBABLE SYNTHETIC SUTURES |
| **Intended Purpose:** | NYLON suture is used to suture and ligate general soft tissues. SUPRAMID NYLON suture is used to suture and ligate general soft tissues. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | H010202 - NON-ABSORBABLE NON-SYNTHETIC SUTURES |
| **Intended Purpose:** | SILK suture is used to suture and ligate general soft tissues. STAINLESS STEEL suture is used for soft tissue approximation, bone tissue approximation and/or fixation. |

| | |
|---|---|
| **The validity of this certificate depends on conditions and/or is limited to the following:** | -none- |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-02-19 | BJ20092603 | Initial issuance |



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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

2024/05/21

**Notified Body Confirmation Letter**

**Reference: EU2023-607/[ID 869672]**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following 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 Number (if available):

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **N/A** | N/A | N/A | N/A |

**Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| ***Synthetic Absorbable Suture With or Without Needle (WEGO-PGA RAPID)*** | *Class III* | *Not Applicable* | *MDD Certificate #1 : M.2017.106.8802 expiry date: 2024/05/27 NB# : 2292*<br><br>*MDD Certificate #2: M.2017.106.8802-1 expiry date: 2024/05/27 NB# : 2292* |
| ***Synthetic Absorbable Suture With or Without Needle (WEGO-PGLA RAPID)*** | *Class III* | *Not Applicable* | *MDD Certificate #1 : M.2017.106.8802 expiry date: 2024/05/27 NB# : 2292*<br><br>*MDD Certificate #2: M.2017.106.8802-1 expiry date: 2024/05/27 NB# : 2292* |
| ***Synthetic Absorbable Suture With or Without Needle (WEGO-PGLA)*** | *Class III* | *Not Applicable* | *MDD Certificate #1 : M.2020.106.13488 expiry date: 2024/05/27 NB# : 2292*<br><br>*MDD Certificate #2: M.2020.106.13488-1 expiry date: 2024/05/27 NB# : 2292* |

## Confirmation Letter Revision History

| Date | Action |
|---|---|
| 2024/05/21 | Initial issue |
| | |
| | |



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Chucun Town, Torch Hi-Tech Science Park
No. 8-1, Weigao West Road
264200 WEIHAI, SHANDONG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

| Your reference/letter of | Our reference/name | E-mail | Tel. extension | Date | Page |
|---|---|---|---|---|---|
| 065765 | 713319745 | Jingling.Chen@tuvsud.com | +86 1862 222 3256 | 2024-04-25 | 1 of 6 |

**TÜV SÜD Product Service GmbH**
**Confirmation Letter**

**CL 065765 0032 Rev. 01**

**Reference: 713319745 | BJ24092602-CL**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

**SRN Number: CN-MF-000006957**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below:

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: www.tuvsud.com/ps-cert?q=cert:CL 065765 0032 Rev. 01

In case of inquiries please contact: medical_devices@tuvsud.com

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-25

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Jinglin Chen
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Konrad Fackler
Application Reviewer

**Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified during application review) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Device 1**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-NYLON)**<br><br>**Basic UDI-DI:**<br>69418136NA-suture- sIIbN7R | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0023 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Device 2**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-SUPRAMID NYLON)**<br><br>**Basic UDI-DI:**<br>69418136NA-suture- sIIbV89 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0023 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Device 3**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-SILK)**<br><br>**Basic UDI-DI:**<br>69418136NA-suture- sIIbS83 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0023 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified during application review) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Device 4**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-STAINLESS STEEL)**<br><br>**Basic UDI-DI:**<br>69418136NA-suturesIIb- GSDZ | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0023 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Device 5**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-POLYESTER)**<br><br>**Basic UDI-DI:**<br>69418136NA-suturesIIbE77 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0018 Rev. 02<br>G7 065765 0014 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Device 6**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-POLYPROPYLENE)**<br><br>**Basic UDI-DI:**<br>69418136NA-suturesIIbP7V | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0018 Rev. 02<br>G7 065765 0014 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified during application review) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Device 7**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-PTFE)**<br><br>**Basic UDI-DI:**<br>69418136NA-suturesIIbZ8H | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0018 Rev. 02<br>G7 065765 0014 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Device 8**<br><br>**Non-Absorbable Surgical Suture With or Without Needle (WEGO-PVDF)**<br><br>**Basic UDI-DI:**<br>69418136NA-suturesIIbPVF2 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number: | ☒ Certification as follows:<br><br>Certificate #:<br>G1 065765 0018 Rev. 02<br>G7 065765 0014 Rev. 02<br>NB #0123 (TÜV Süd)<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |

**Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified during application review) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Not applicable** | ☒ N/A | ☒ N/A | ☒ N/A |

## Confirmation Letter Version History

| Date | TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2023/12/08 | BJ23092600-CL | Initial issue |
| 2024/04/25 | 713319745 \| BJ24092602-CL | New revision to add device 5, 6, 7 and 8 (PE/PP/PTFE/PVDF sutures) |

**UDEM Adriatic d.o.o.**
Radnička cesta 54/R3
10000 Zagreb, CROATIA

**2024/03/05**

**FOOSIN MEDICAL SUPPLIES INC., LTD.**
**No.20,Xingshan Road,**
**Weihai Torch Hi-tech Science Park,**
**264210 Weihai, Shandong Province,**
**PEOPLE'S REPUBLIC OF CHINA**

**NOTIFIED BODY CONFIRMATION LETTER**

**Reference: 2024.MDR.1621.NBCL.0095**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2022/10/10) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2022/10/10) with the following manufacturer:

FOOSIN MEDICAL SUPPLIES INC., LTD.
No.20,Xingshan Road,
Weihai Torch Hi-tech Science Park,
264210 Weihai, Shandong Province,
PEOPLE'S REPUBLIC OF CHINA
SRN Number (if available): CN-MF-000006957

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

UDEM Adriatic d.o.o.
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In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager

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**Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD device | MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **N/A** | N/A | N/A | N/A |

**Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD device | MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Synthetic Absorbable Suture (WEGO-PDO)** | Class III | N/A | **<u>Certificate 1:</u>**<br>Full Quality Assurance System Certificate No:<br>M.2020.106.13488<br><br>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)<br><br>**<u>Certificate 2:</u>**<br>EC Design-Examination Certificate No:<br>M.2020.106.13488-1<br><br>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292) |
| **Synthetic Absorbable Suture(WEGO-PGCL)** | Class III | N/A | **<u>Certificate 1:</u>**<br>Full Quality Assurance System Certificate No:<br>M.2017.106.8802<br><br>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)<br><br>**<u>Certificate 2:</u>**<br>EC Design-Examination Certificate No:<br>M.2017.106.8802 -1 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD device | MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| | | | UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292) |

## Confirmation Letter Revision History

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024/03/05 | 2024.MDR.1621.NBCL.0095 | Initial issue |
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