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TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

**Weigao Medical International Co., Ltd.  
No.1 Weigao Road  
High-tech Industrial Development Zone  
264210 Weihai, Shandong Province  
PEOPLE'S REPUBLIC OF CHINA**

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
087117	713336173 713343073			2024-07-26	1 of 5
		medical_devices@tuvsud.com			

**TÜV SÜD Product Service GmbH  
Confirmation Letter  
CL 087117 0020 Rev. 01**

**Reference: 713336173, 713343073**

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-000011328

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.

**Registered Office: Munich**  
Trade Register Munich HRB 85 742  
UniCredit Bank AG · BIC HYVEDEMMXXX  
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(Germany) at tuvsud.com/imprint

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Walter Reithmaier (CEO)  
Patrick van Welij

**TÜV SÜD Product Service GmbH**  
Ridlerstr. 65  
80339 Munich  
Germany

**tuvsud.com/ps**  
Hotline: +49 89 50084-747





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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see <http://www.tuvsud.com/ps-cert?q=cert:CL 087117 0020 Rev. 01>

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com).

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
2024-07-26

TÜV SÜD Product Service GmbH  
Medical and Health Services

TÜV SÜD Product Service GmbH  
Medical and Health Services

Xingchun Li  
Xingchun Li (Jul 29, 2024 09:21 GMT+8)

Mr. Xingchun Li  
Conformity Assessment Responsible (CARE)

Matthias Mumme  
Matthias Mumme (Jul 29, 2024 10:36 GMT+2)

Matthias Mumme  
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
<b>Device 1</b> <b>Sterile High Pressure Angiographic Syringes for Single Use</b> <b>697034977WGGF1022A012AU</b>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 2</b> <b>Sterile Hypodermic Syringes for single use</b> <b>697034977WGGF1062A010CC</b>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: 2.5ml, 25ml	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 3</b> <b>Sterile Hypodermic Syringes for Single Use Without Needle</b> <b>697034977WGGF1011S015E8</b>	<input checked="" type="checkbox"/> Class I devices with measuring function	<input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: 2.5ml, 25ml	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 4</b> <b>Sterile Infusion Sets for Single Use</b> <b>697034977WGGF1072B011D2</b>	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 5</b> <b>Insulin Pen Needle</b> <b>697034977ZJKDL062A0024G</b> <b>697034977ZJKDL062A0164T</b>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: 28G, 29G, 30G	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 6</b> <b>Syringes for insulin</b> <b>697034977ZJKDL062A0034J</b> <b>697034977ZJKDL062A0174V</b>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 7</b> <b>Scalp Vein Sets</b> <b>697034977ZJKDL062A0044L</b> <b>697034977ZJKDL072B0095J</b>	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 8</b> <b>Disposable Needles</b> <b>697034977ZJKDL062A0054N</b> <b>697034977ZJKDL072A00757</b>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: 14G, 15G, 16G, 17G, 31G, 32G, 33G, 34G	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
<b>Device 9</b> <b>Blood Collecting Needle</b> <b>697034977ZJKDL062A0064Q</b>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123



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
697034977ZJKDL062A0304M		Individual Article number: 26G	
Device 10 Fistula Needle 697034977ZJKDL072B0085G	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 11 Extension Tube for Single Use 697034977WGGF1021S013EH	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G2S 087117 0014 Rev.02 NB 0123
Device 12 Sterile Oral/Enteral Syringe for Single Use 697034977WGGF1022A021AV	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 13 Sterile Transfusion Sets for Single Use 697034977WGGF1072A022CY	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 14 Plastic blood bags for single use 697034977WGGF1182B023E7	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 15 I.V.Catheter for single Use 697034977WGJR1072A024QF0014	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 16 Tracheal Tubes 697034977GDYK1052A018AX	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 17 Urethral catheter 697034977GDYK1052A019AZ	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 18 Silicone Foley Catheters 697034977GDYK1052A020AJ	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 19 Sterile Heparin Cap for single use 697034977SZHEX041S027LA	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G2S 087117 0014 Rev.02 NB 0123
Device 20	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01



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
Stopcock for Single Use (with Extension Tube) 697034977SZHEX022A029FZ			NB 0123
Device 21 Stopcock for Single Use 697034977SZHEX022A031FL	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 087117 0013 Rev.01 NB 0123
Device 22 Sterile Infusion Connector without Needles for single use 697034977SZHEX011S028K5	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G2S 087117 0014 Rev.02 NB 0123

**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	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A

#### Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-06-26	713336173	Initial issue
2024-07-26	713336173 713343073	Corrected Class of Device 20 and 21 from Is to IIa Added Device 22