



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System  
 Directive 93/42/EEC on Medical Devices (MDD), Annex V  
 (Devices in Class IIa, IIb or III)

**No. G2 081232 0010 Rev. 02**

**Manufacturer:**

**AnHui Hongyu Wuzhou  
 Medical Manufacturer Co.,Ltd.**

No.2 Guanyin Road  
 Economic Development Zone  
 Taihu County  
 246400 Anqing, Anhui  
 PEOPLE'S REPUBLIC OF CHINA

**Product  
 Category(ies):**

**Sterile Hypodermic Syringes for Single Use, Sterile  
 Hypodermic Needles for Single Use, Sterile Insulin Syringes  
 for Single Use, Insulin Pen-injectors for Medical Use,  
 Transfusion Sets for Single Use, Infusion Sets for Single  
 Use(Gravity Feed), Burette-type Infusion Sets for Single Use,  
 Intravenous Needles for Single Use, Blood Collection  
 Needles for Single Use, Sterile Dental Injection Needles for  
 Single Use, Disposable Precision Flow Regulator, Insulin Pen  
 Needles for Single Use, Blood Collection Sets for Single Use,  
 Sterile Safety Hypodermic Needles for Single Use, Safety  
 Blood Collection Sets for Single Use, Safety Blood Collection  
 Needles for Single Use**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** SH19735EXT01

**Valid from:** 2020-03-03

**Valid until:** 2024-05-26

**Date,** 2020-03-03

Christoph Dicks  
 Head of Certification/Notified Body

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



**Add value.  
Inspire trust.**

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

AnHui Hongyu Wuzhou  
Medical Manufacturer Co.,Ltd.  
No.2 Guanyin Road  
Economic Development Zone  
Taihu County  
246400 ANQING, ANHUI  
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	713300174 / GCN-SH24735A02	+86 21 6141 0162 liang.lu@tuvsud.com		2024-03-23	1 of 7

**TÜV SÜD Product Service GmbH  
Confirmation Letter  
CL 081232 0013 Rev. 01**

**Reference: 713300174 / GCN-SH24735A02**

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-000029789

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.

**Registered Office: Munich**  
Trade Register Munich HRB 85 742  
UniCredit Bank AG · BIC HYVEDEMMXXX  
IBAN DE13 7002 0270 0048 8522 11  
VAT ID No. DE129484267  
Information pursuant to § 2 [1] DL-InfoV  
(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

**TÜV®**



- 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)

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 [www.tuvsud.com/ps-cert?q=cert:CL\\_081232\\_0013\\_Rev.01](http://www.tuvsud.com/ps-cert?q=cert:CL_081232_0013_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,  
2024-03-23

TÜV SÜD Product Service GmbH  
Medical and Health Services

A handwritten signature in black ink, appearing to be 'Liang Lu', written over a horizontal line.

Mr. Liang Lu  
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH  
Medical and Health Services

A handwritten signature in black ink, appearing to be 'Claus Matthias Mumme', written over a horizontal line.

Claus 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 hypodermic syringes for single use</b> <b>(Basic UDI -DI: 69586976HWZSQ0015C)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 2</b>  <b>Sterile hypodermic needles for single use</b> <b>(Basic UDI -DI: 69586976HWZSZ0017B)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 3</b>  <b>Sterile insulin syringe for single use</b> <b>(Basic UDI -DI: 69586976HWINS001V3 69586976HWINS002V5)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 4</b>  <b>Infusion sets for single use (Gravity feed)</b> <b>(Basic UDI -DI: 69586976HWSYQ0014K)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; 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
	<input type="checkbox"/> Class III implantable custom-made-device		
<b>Device 5</b>  <b>Infusion sets for single use (DEHP free)</b> <b>(Basic UDI -DI: 69586976HWDFSQ0019G)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 6</b>  <b>Intravenous needles for single use</b> <b>(Basic UDI -DI: 69586976HWSYZ0016J)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 7</b>  <b>Sterile safety hypodermic needles for single use</b> <b>(Basic UDI -DI: 69586976HWAQZSZ002GC)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 8</b>  <b>Insulin Pen Needles for Single Use</b> <b>(Basic UDI -DI: 69586976HWYDZ001ZN)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; 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
<b>Device 9</b>  <b>Transfusion sets for single use (Basic UDI -DI: 69586976HWSXQ00148)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 10</b>  <b>Burette-type infusion sets for single use (Basic UDI -DI: 69586976HWDDGSYQ00133)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 11</b>  <b>Blood collection needles for single use (Basic UDI -DI: 69586976HWCXZ001XL)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 12</b>  <b>Sterile dental injection needles for single use (Basic UDI -DI: 69586976HWYKZ00146)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 13</b>	<input type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows:



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>Blood Collection Sets for Single Use</b> <b>(Basic UDI -DI: 69586976HWJMCX001EM)</b>	<input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 14</b>  <b>Safety Blood Collection Sets for Single Use,</b> <b>(Basic UDI -DI: 69586976HWAQJMCX001ZN)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 Rev. 02; NB# 0123
<b>Device 15</b>  <b>Safety Blood collection needles for single use</b> <b>(Basic UDI -DI: 69586976HWAQCXZ0018N)</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 081232 0010 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
2024/01/24	713300174	Initial issue
2024/03/23	713300174 / GCN-SH24735A02	Add Device 8 to Device 15