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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 109397 0004 Rev. 00

Manufacturer:

Xuchang Zhende Surgical Dressing Co., Ltd.
Area A, Baihua Road East
South Side of Erji river
Industry Cluster District
Yanling County
461200 Xuchang Henan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Lap Sponge,
Gauze Products with X-ray thread,
Gauze Products without X-ray thread,
Non Woven Products with X-ray thread,
Non Woven Products without X-ray thread
Procedural Dressing Trays
(see the details in next page)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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:G1 109397 0004 Rev. 00

Report No.: SH2049502

Valid from: 2020-11-10
Valid until: 2024-03-03
Date, 2020-11-10

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 109397 0004 Rev. 00

Product(s)/Product Category(ies)

- **Gauze Products with X-ray thread**

  Gauze Swab, Gauze Sponge, Gauze Roll, Gauze Ball, Zig-zag Gauze, Gauze

- **Gauze Products without X-ray thread**

  Gauze Swab, Gauze Sponge, Gauze Roll, Gauze Ball, Zig-zag Gauze, Gauze

- **Non-woven Products with X-ray thread**

  Non-woven Swab, Non-woven Sponge, Non-woven Ball

- **Non-woven Products without X-ray thread**

  Non-woven Swab, Non-woven Sponge, Non-woven Ball

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Xuchang Zhende Surgical Dressing Co., Ltd.

Self-Declaration on MDD Extension and MDR Application

We, Xuchang Zhende Surgical Dressing Co., Ltd., declare the compliance of the Procedural Dressing Trays with EU regulation 2023/607. This self-declaration on MDD extension and MDR application is issued under the sole responsibility of Xuchang Zhende Surgical Dressing Co., Ltd.

The CE certificate covering the above-mentioned products is G1 109397 0004 Rev. 00 and expires on March 3rd 2024.

We hereby declare the above-mentioned products:

- Continue to comply with the Directive 93/42 EEC;
- Have no significant changes in design or intended purpose
- Have no safety concerns

We also declare that the MDR Stage 2 Audit has been completed on October 31st 2023, and MDR certificate is being issued by the Notified Body. We also submitted the application for extension on November 17th 2023, and expect to receive the confirmation letter before March 3rd, 2024, and the conditions for extension according to 2023/607 are fulfilled.

Once the extension is approved by the Notified Body, a confirmation letter will be issued and extension could last until 31 December 2028.

Xuchang Zhende Surgical Dressing Co., Ltd.
January 23rd, 2024

Add value.
Inspire trust.

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

Xuchang Zhende Surgical
Dressing Co., Ltd.
Industry Cluster District
Area A, Baihua Road East
South Side of Erji river
Yanling County
461200 XUCHANG HENAN
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	GCN-SH24495A01 / SH2449500_CL	Yu.Qiu@tuvsud.com		2024-05-13	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 109397 0010 Rev. 00

Reference: GCN-SH24495A01 / SH2449500_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-000009222

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)

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 109397 0010 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-13

TÜV SÜD Product Service GmbH
Medical and Health Services

Yu Qiu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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
Device 1 **Gauze Products** **(Basic UDI -DI:** **697240330GP0000014T)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 109397 0004 Rev.00; NB# 0123
Device 2 **Lap Sponges** **(Basic UDI -DI:** **697240330LS0000019D)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 109397 0004 Rev.00; NB# 0123
Device 3 **Wound Dressing Kit** **(Basic UDI -DI:** **697240330WDK000010R8** **697240330WDK000005RF)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 109397 0004 Rev.00; NB# 0123
Device 4 **Sterile Gauze Products** **(Basic UDI -DI:** **697240330SGP000001SR)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate # G2S 109397 0005 Rev. 00; 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
	☐ Class III implantable custom-made-device		
Device 5 **Non-woven Products** **(Basic UDI -DI:** **697240330NP00000292** **697240330NS000005AT** **697240330NS000006AV** **697240330NS000007AX** **697240330NS000008AZ** **697240330NB000002ZH** **697240330NP0000018Y** **697240330NS000001AK** **697240330NS000002AM** **697240330NS000003AP** **697240330NS000004AR** **697240330NB000001ZF)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 109397 0004 Rev.00; NB# 0123
Device 6 **Sterile Non-noven Products** **(Basic UDI -DI:** **697240330SNP000001WW** **697240330SNS000001YH** **697240330SNS000002YK** **697240330SNS000003YM** **697240330SNS000004YP** **697240330SNB000001PG)**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G2S 109397 0005 Rev. 00; 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	**☒ 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
2024-05-13	GCN-SH24495A01 / SH2449500_CL	Initial issue