Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 066729 0004 Rev. 01

Manufacturer:

Jiangsu Suyun Medical Materials Co., Ltd.
No.18 Jin Qiao Road
Dapu Industrial Park
222002 Lianyungang, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G2S 043337 0044 Rev. 03

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 066729 0004 Rev. 01

Report No.: BJ23088501

Valid until: 2024-04-13

Issue Date: 2023-10-25

Christoph Dicks
Head of Certification/Notified Body

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Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 066729 0004 Rev. 01

Product Category(ies): Sterile Vaginal Speculum for Single Use, Sterile Gynaecological Collectors for Single Use, Sterile Rectal Catheter for Single Use, Sterile Nasal Speculum for Single Use, Sterile Urine Drainage Bag for Single Use, Sterile Applicator with Cotton Tip, Sterile Tongue Depressor, Sterile Otolaryngological Set for single use, Sterile Gynecological Kit for Single Use, Medical Transport Swab, Sterile Catheter Tip Syringe for Single Use, Sterile Extension Tube for Single Use, Sterile Laryngological Speculum for Single Use, Sterile Umbilical Cord Clamp for Single Use, Sterile Amniohook for Single Use, Ear funnel, Forceps, Ostomy bags and accessories.Sterile Holder Accessories for Single Use (Fastener, Arm Drape).

Description of Change: Change of product name from Transport Swab to Medical Transport Swab.

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

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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 043337 0044 Rev. 03

Manufacturer

Jiangsu Suyun Medical Materials Co., Ltd.
No.1 Medicine Lane, Renmin Rd.
222002 Lianyungang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Sterile Non-active Medical devices (For detailed information see attachment).

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: BJ1888504

Valid from: 2019-05-27
Valid until: 2024-04-13

Date, 2019-05-27

Stefan Preiß
Head of Certification/Notified Body

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

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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 043337 0044 Rev. 03

Facility(ies):

Jiangsu Suyun Medical Materials Co., Ltd.
No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang,
PEOPLE'S REPUBLIC OF CHINA

Jiangsu Suyun Medical Materials Co., Ltd
No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Attachment:

Sterile Vaginal Speculum for Single Use, Sterile Gynaecological Collectors for Single Use, Sterile Rectal Catheter for Single Use, Sterile Nasal Speculum for Single Use, Sterile Urine Drainage Bag for Single Use, Sterile Applicator with Cotton Tip, Sterile Tongue Depressor, Sterile Otolaryngological Set for single use, Sterile Gynecological Kit for Single Use, Transport Swab, Sterile Catheter Tip Syringe for Single Use, Sterile Extension Tube for Single Use, Sterile Laryngological Speculum for Single Use, Sterile Umbilical Cord Clamp for Single Use, Sterile Amniohook for Single Use, Ear funnel, Forceps, Ostomy bags and accessories.Sterile Holder Accessories for Single Use (Fastener, Arm Drape).

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

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Jiangsu Suyun Medical Materials
Co., Ltd.
Dapu Industrial Park
No.18 Jin Qiao Road
222002 LIANYUNGANG, JIANGSU PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension	Email	Date	Page
CBW 66729	GCN-BJ23885A02	+86-10-6590-6186	Xingchun.Li@tuvsud.com	2024-02-06	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 066729 0006 Rev. 00

Reference: GCN-BJ23885A02

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: CN-MF-000021132

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 066729 0006 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
06.02.2024

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Li Xingchun
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Arianit Fazlija
2024.02.06 10:23:39 +01'00'

Arianit Fazlija
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
Sterile Vaginal Speculum for single use 69332982004	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Gynaecological Collectors for single use 69332982028	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Rectal Catheter for single use 69332982011	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Nasal Speculum for Single Use 69332982016	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Sterile Urine Drainage Bag for single use 69332982019	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Applicator with Cotton Tip 69332982066	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Tongue Depressor 69332982065	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Otolaryngological Set for Single use 69332982069	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☒ N/A	☒ Certification as follows: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 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
	☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Sterile Gynecological kit for single Use 69332982057	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Medical Transport swab 69332982073	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Catheter Tip Syringe for Single Use 69332982017	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Extension Tube for single use 69332982074	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 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
	☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Sterile Laryngological Speculum for Single use 69332982083	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Umbilical Cord Clamp for single use 69332982080	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Sterile Amniohook for single use 69332982044	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Ostomy bags and accessories 69332982163	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: No.G2S 043337 0044 Rev.03;

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 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		No.GCQ066729 0004 Rev.01; NB#0123
Forceps 69332982041	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; NB#0123
Ear funnel 69332982043	☐ 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: No.G2S 043337 0044 Rev.03; No.GCQ066729 0004 Rev.01; 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
☒ N/A	☒ 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
2024/02/06	GCN-BJ23885A02	Initial issue