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 060834 0022 Rev. 01

Manufacturer

Longbow First Aid Products Manufactory
2/F, Area C, HanTian Industrial Park
Guiping Road
Guicheng Subdistrict
Nanhai District
528200 Foshan City, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Gauze Compresses, Medical Dressings,
Transparent Adhesive Dressings,
Roller Gauze, Dressing Pads,
Non-adherent Dressings,
Cavity Wound Dressings,
Dressing Bandage,
Irrigation Set,
Eye Wash

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. 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:G2S 060834 0022 Rev. 01

Report No.: SH2049602

Valid from: 2021-02-02
Valid until: 2024-05-26

Date, 2021-02-02

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

LONGBOW 佛山朗博医疗救护用品有限公司
LONGBOW FIRST AID PRODUCTS MANUFACTORY
Add: 2/F, A3 Building, Hantian Industrial Park, Guiping Road, Guicheng sub district, Nanhai district, 528200 Foshan City, Guangdong Province, CN
Web: www.chinalongbow.com **E-mail:** subella@chinalongbow.com

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Longbow First Aid Products manufactory
Manufacturer address and contact details	2/F,Area C,HanTian Industrial Park, Guiping Road,Guicheng Subdistrict, Nanhai District, 528200 Foshan City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA Contact: Subella Email: subella@chinalongbow.com
Single Registration Number (SRN) (if available)	CN-MF-000032024

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH (Europe)
Authorised Representative address and contact details	Eiffestrasse 80, 20537 Hamburg, Germany

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Web: www.chinalongbow.com **E-mail:** subella@chinalongbow.comw.com

Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐Expired *before* 20 March 2023:

  ☐Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

☐A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

☐A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

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☑Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☑A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☐A QMS in accordance with Article 10(9) MDR is in place.
☐A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name: Longbow First Aid Products Manufactory

Location & Date: Foshan/10/05/2024

Signature:

Print Name: He Junli

Title: Sales Manager

Contact Details (at least email) Jenny@chinalongbow.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Hydrogel Dressing	**G1 060834 0025 Rev. 00**	**26 May 2024**	**0123**	**TÜV SÜD Product Service GmbH**	**31 December 2028**	
Eye Wash	**# G2S 060834 0022 Rev. 01**	**26 May 2024**	**0123**	**TÜV SÜD Product Service GmbH**	**31 December 2028**	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Declaration of Conformity

MANUFACTURER: Longbow First Aid Products Manufactory

ADDRESS: 2/F,Area C,HanTian Industrial Park,Guiping Road,Guicheng Subdistrict Nanhai District,Foshan City,528200,Guangdong Province, China

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)

ADDRESS: Eiffestrasse 80, 20537, Hamburg,, Germany

PRODUCT : 0.9 % STERILE SODIUM CHLORIDE WATER

Mode11: 5ml,10ml,15ml,20ml,30ml,100ml,250ml,500ml

UMDNS code: 11655
Classification (MDD, Annex IX): I sterile, rule 5
Conformity Assessment Route: Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices.
Standard Applied: See attached list of (Harmonized –EN) standards for which documented evidence of compliance can be provided.

Notified Body:	TÜV SÜD Product Service GmbH
Address:	Ridlerstr. 65, 80339 MÜnchen, Germany
Identification number:	CE 0123
(EC) Certificate(s):	G2S0608340022
Expire date of the Certificate:	2024-05-26
Start of CE Marking:	2021-02-02
Place, Date of Issue:	Foshan City, Guangdong Province, China

Signature:
Name: General Manager Longman Dong
Position: Foshan City, Guangdong Province, China