
NaCl 0,9%
Sodium chloride solution
NaCl 0,9%
500ml
REF SOL004
240301
280201
STERILE R
MD

LONGBOW FIRST AID MANUFACTORY

DATA SHEET

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Establishment Department	Quality Inspection Department

	Name (Printed)	Date
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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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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

0.9% Sterile Sodium Chloride water is a non-invasive medical device which intended to used for emergency eye, epidermis wound cleansing. It is only for short term（no more than 60 minutes）first aid use.

1. Range

This standard specifies the product classification, requirements, testing methods, inspection rules, signs, labels, as well as packaging, transportation and storage requirements.

2. Normative Reference Documents

Reference Standard	MDD 93/42 EEC	EN ISO 11737-2:2009
	EN 15223.1-2012	EN ISO 11137-1:2015
	EN 1041:2008	EN ISO 11137-2:2013
	EN ISO 10993-1:2009	ENISO13485-2016
	EN ISO 10993-5:2009	EN ISO 14644-1:2015
	EN ISO10993-10:2013	EN ISO 14971:2012
	EN ISO 11607-1:2009	Meddev 2.7.1
	EN ISO 11607-2:2006	ASTM 1980:2016
	EN ISO 11737-1:2009	EN 980

3. Classification

0.9% Sterile Sodium Chloride water shall conform to the requirements of this standard and be manufactured in accordance with the technical documents approved by the prescribed procedures.

3.1 The basic size of the 0.9% Sterile Sodium Chloride water shall conform to the requirements of table 1.

Code	Specification	Solution Weight	Tolerance	Bottle size
LB-YS1000	1000ml	1000ml	±5%	9.3x7.5x23cm
LB-YS500	500ml	500ml	±5%	Φ7.7x17.8cm
LB-YS250	250ml	250ml	±5%	Φ6.5x16.2cm
LB-YS100	100ml	100ml	±5%	Φ5x12.1cm
LB-YS030	30ml	30ml	±5%	1.8x3.7x11.4cm
LB-YS020	20ml	20ml	±5%	1.8x2.2x11.4cm
LB-YS015	15ml	15ml	±5%	1.8x2.2x9.5cm
LB-YS010	10ml	10ml	±5%	1.8x2.2x7.5cm
LB-YS005	5ml	5ml	±5%	1.8x2.2x5.6cm

3.2 Product composition

Product name	Ingredient
0.9% Sodium Chloride water	Nacl 0.9%w/v (BP), purified water 99.1%.

4.Requirements

4.1.a. Appearance

Clear liquid

4.3.b. Capacity

Tolerance ± 5%

4.1.c. Content determination

The content of sodium chloride solution should be 0.85%g/ml-0.95%g/ml

4.1.d. pH value

pH range is 4.5-7.4

4.1.e. Aseptic requirements

Aseptic (SAL 10^{-6}) packaging complete

4.1.f. Biological evaluation

(a) Cytotoxicity should not be greater than one level.

(b) There should be no skin irritation.

(c) There should be no sensitization reaction.

	Self Test / Subcontract Test	Institutions
Appearance	Self Test	/
Capacity	Self Test	/
Content determination	Self Test	/
pH value	Self Test	/
Aseptic requirements	Self Test & Subcontract Test	Pony Testing International Group
Biological evaluation	Subcontract Test	Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration
Workshop environment	Subcontract Test	Foshan SDA

5. Inspection Rules

5.1 0.9% Sterile Sodium Chloride water shall be inspected by the company's quality inspection Department.

5.2 0.9% Sterile Sodium Chloride water must be submitted in batches for inspection, inspection for factory inspection (batch check) and type inspection (cycle check)

5.3 Factory inspection (batch check)

5.3.1 0.9% Sterile Sodium Chloride water for one batch of production of the same species, specifications of products for a group, each batch of products should be inspected by the company's Quality Inspection Department, qualified to be accompanied by a certificate of the factory.

5.3.2 factory inspection using ISO2859-1:1999 one-time sampling plan, the initial inspection for the normal inspection, its failure classification, inspection level, acceptance quality limit (AQL) according to table 2.

Table 2 Sampling Plan For Factory Inspection

Substandard Category	Class A Substandard	Class B Substandard	Class C Substandard
Check Item	1、5、7、8	2、3、4、6	-
Inspection Level	S-3	S-3	-
Acceptance Quality Limit (AQL)	0.40	0.65	-

5.3.3 Ex-factory, 1, 2, 3, 4, 5, 6, 7 should be inspected, qualified rear can be out of factory.

5.4.Type inspection (cycle inspection)

5.4.1Type inspection in normal circumstances, normally once a year, if one of the following circumstances, should be examined:

a）Before the new product put into production;

b）When there is a major change in design, workmanship, material；

c）Discontinued after one years of production；

d）When the relevant departments supervise and inspect the product quality.

5.4.2According to ISO 10993-1:2009, the biological evaluation should be combined with the nature and variability of materials used in manufacturing equipment, other non clinical trials, clinical studies and post-IPO conditions.

Note: The purpose of this section is to avoid redundant duplication of experiments when information about materials and/or equipment is available from other parties.

5.4.3 The type test adopts ISO2859-1:1999 a sampling scheme, the discriminant level is I, its unqualified classification, the judgement array and the unqualified quality level according to the stipulation of table 3.

Table 3 Sampling Scheme For Type Inspection

Unqualified classification	Class A unqualified	Class B Unqualified	Class C Unqualified
Check Project	1、5、7、8	2、3、4、6	-
Determinant array	n=100（Ac＝0,Re＝1）	n＝8（Ac＝0,Re＝1）	-
Unqualified quality level(RQL)	1.0	12	-

5.4.4 All the test group in the type of inspection qualified for the type of inspection, otherwise the type of inspection unqualified.

6. Test methods

6.1 Specification size, appearance

The results should be in line with the product requirements by measuring the general gage.

6.2 Core requirements

Check the qualification of materials supplied by the raw material supplier (Certificate of production enterprise, product registration certificate, test Report), and the result should conform to the requirement of biocompatibility.

6.3 Content determination

Extract the product 10ml, add 40ml water and 2% paste Liquid 5ml, 2. 5% borax solution 2m l and fluorescence yellow indicator liquid 5-8 drops, with nitric acid Titration (0. Lm o l/l) titration.Each lm l nitrate drip (0.lm o l/l) phase When 5. 844mg NaCl. The results should conform to the product requirements.

6.4 Loading capacity

Weighing the results should be in line with the product requirements.

6.5 Packaging integrity

In accordance with the methods specified in ASTM D3078, the results conform to product requirements.

6.6 pH value

Measured using pHS-25 type ph meter.

（1）Instrument Calibration：Select two standard buffers (the pH difference between the two is about 3, and the range can cover the pH value of the water sample) to correct the pH meter.

（2）PH Value Determination：Rinse the electrodes and place them into a proper sample, (each specimen should be washed and dried by the electrodes first), shaking the specimen evenly, and reading the ph value and recording the temperature after the sample is stabilized.

The results should conform to the product requirements.

6.7 Aseptic

In accordance with the method specified in En iso11737-2:2006, the results shall conform to aseptic requirements (sterility guarantee level10^{-6}).

6.8 Biological evaluation

In accordance with the methods specified in ISO 10993.10-2010, 10993.5-2009, the results shall conform to the biocompatibility requirements.

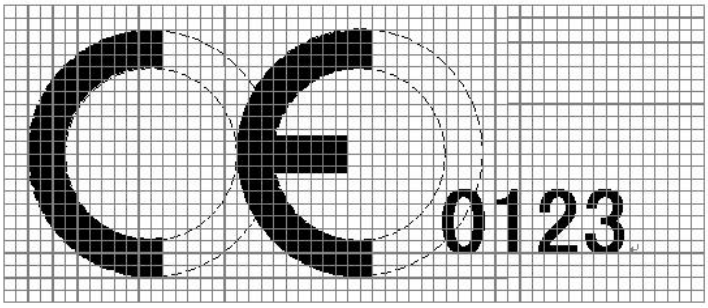
7. Signs, labels and precautions

7.1 Signs

7.1.1 The following information should be indicated in the package

a.Names and addresses of manufacturers and EC representatives.
b.Scope of application, intended use and prohibited products.
c.Sterilization method
d.Failure period
e.Production Batch Number
f.Disposable words
g.Special storage and/or handling conditions
h.Warning Flag
i.Product model Sign

7.1.2 The design of CE logo shall conform to the requirements of/Annex XII. It is sterile and be has CE0123 markings.



a.Magnification and reduction shall conform to the proportions of the above drawings;
b.The height of the symbol should not be less than 5 mm.
For small devices, the minimum size is not limited by it.

7.1.3 Considerations

a.Do not put the burn dressing in the affected area.
b.Do not reuse.
c.External use only.
d.If allergic reactions occur, please stop using them.
e.Store in a cool place.
f.If the wrapper is turned on or damaged, do not use.
g.Seek medical assistance.
h.Medical waste Treatment.

8. Packaging, Transportation, Storage and Shelf life

8.1 The Outer packing box should have a copies and a certificates of qualification.
8.2 The number and specification of the corrugated box should be in accordance with the quantity and specification of the packing.
8.3 Transportation, storage should be extruded, sharp collision, sunshine direct drying and rain.
8.4 The 0.9% Sterile Sodium Chloride water has a shelf life of five years from the date of production and must be in the sterilization period.

Product Standard for Eyewash

1. Product Overview and standard task source, background

0.9% Sterile Sodium Chloride water is a very popular medical device. It has a long history of usage. This medical device is a non-invasive medical device which intended to used for emergency eye, epidermis wound cleansing. It is only for short term（no more than 60 minutes）first aid use.

We use Blow Fill Seal (BFS) technology to produce our 0.9% Sterile Sodium Chloride water. The basic concept of BFS is that a container is formed, filled and sealed in a continuos process without human intervention, in a sterile enclosed area inside the machine. Thus, this technology can be used to aseptically manufacture sterile pharmaceutical liquid dosage forms. Moreover, we use gamma ray to sterilize the final products at the end to ensure our products' quality.

2. Basis for Management category determination

According to DIRECTIVE 93/42/EEC, Annex IX, rule 1 "All non-invasive devices are in class I, unless one of the rules set out hereinafter applies ",the device is non-invasive device, and it is not within the scope of hereinafter applies rules. So this medical device belongs to class I.

3. The determination basis of main performance index

About Technical performance requirements

This product technology mature, the development personnel many years medical device product design experience, similar product in the clinical application has been many years, has not seen regarding the product adverse event report and the serious product fault complaint's public apology, this kind of product structure principle is simple, the function mechanism is mature, therefore the company has consulted some similar products at home and abroad, and to the clinician to understand the clinical application situation, according to the related request, the comprehensive analysis determines.

4. Material Safety basis

0.9% Sodium Chloride

It is sterile solution of Nacl 0.9%w/v (BP), purified water 99.1%. It has been written in BP and used in clinical. Its safety and reliability has been proved. It will not have any harm to the human body.

5. Reference standards, information

Reference standard in the body part of this standard.

MDD 93/42 EEC:2016
EN 15223.1-2012
EN 1041:2013
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 11607-1:2009
EN ISO 11607-2:2006
EN ISO 11737-1:2009
EN ISO 11737-2:2009
EN ISO 11137-1:2006

EN ISO 11137-2:2013

EN ISO 13485-2012

EN ISO 14155-1:2011

EN ISO 14155-2:2009

EN ISO 14971:2012

MEDDEV.12.1 rev8：2013