LONGBOW FIRST AID MANUFACTORY

DATA SHEET

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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.

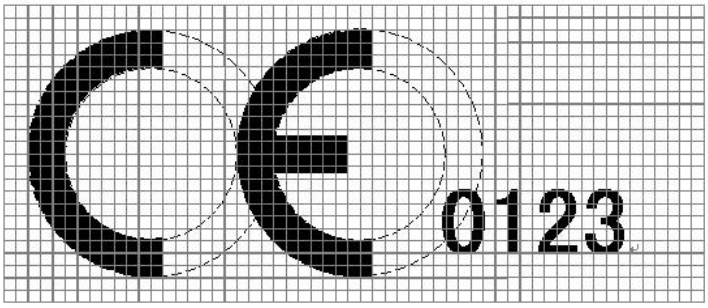
7. Signs, labels and precautions

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