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 (Germany)
ADDRESS：Eiffestrasse 80, 20537, Hamburg，Germany
PRODUCTS: Emergency Burn Dressing

Model: LB-BURN3.5, LB-BURN4, LB-BURN50, LB-BURN60, LB-BURN125, LB-BURN2.5×5, LB-BURN5×15, LB-BRUN10×10, LB-BURN20×20, LB-BURN10×40, LB-BURN20×45, LB-BURN40×60, Face Mask, LB-BURN24x34

GMDN code: 47694
Classification (MDD, Annex II): It is class IIb, rule 4.

Conformity Assessment Route: Annex II Excluding 4

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):	G1 0608340025
Expire date of the Certificate:	2024-05-26
Start of CE Marking:	2021-02-02
Confirmation Letter:	SH2449601
Validity:	2028-12-31

Place, Date of Issue: Foshan City, Guangdong Province, China

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

Add value.
Inspire trust.

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

Longbow First Aid Products Manufactory
Guicheng Subdistrict
2/F, Area C, HanTian Industrial Park
Guiping Road
Nanhai District
528200 FOSHAN CITY, GUANGDONG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension	Email	Date	Page
CBW 60834	SH2449601	+86 21 6141 0162	liang.lu@tuvsud.com	2024-04-22	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 060834 0026 Rev. 00

Reference: SH2449601

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-000032024

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 060834 0026 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
22.04.2024

TÜV SÜD Product Service GmbH
Medical and Health Services

2024.03.06

Liang Lu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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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
Hydrogel Dressing (Basic UDI-DI: 697408409M04040301LBHDRV)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 060834 0025 Rev. 00; NB# 0123
Saline Irrigation Solution (Basic UDI-DI: 697408409Q030103NUSALSL)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2S 060834 0022 Rev. 01; NB# 0123
Eye Wash (Basic UDI-DI: 697408409Q02030299EYEHP)	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G2S 060834 0022 Rev. 01; NB# 0123
Elastic bandages (Basic UDI-DI: 697408409M0303010101EBEB)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 060834 0022 Rev. 01; NB# 012
Non-woven adhesive dressings (Basic UDI-DI: 697408409M04010101LBNAD9F)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 060834 0022 Rev. 01; NB# 012
Gauze compresses (Basic UDI-DI: 697408409M0202010101GCCV)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 060834 0022 Rev. 01; NB# 012
Dressing Pads (Basic UDI-DI: 697408409M04010199DPV2)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 060834 0022 Rev. 01; NB# 012
Non-adherent dressings (Basic UDI-DI: 697408409M040204NADQ8)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 060834 0022 Rev. 01; NB# 012

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> 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
2024/04/22	SH2449601	Initial issue