

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

PRODUCTS: Eye Wash

Model: 20ml,250ml,500ml

UMDNS code: 14462

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. Longbow First Aid Products Manufactory is exclusively responsible for th Doc.

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 Rev.01
Expire date of the Certificate: 2024-05-26
Start of CE Marking: 2017-01-23
Place, Date of Issue: Foshan City, Guangdong Province, China

Signature: _____

Name: General Manager Longman Dong

Position: Foshan City, Guangdong Province, China





EC Declaration of conformity

Manufacture:

Reliance Medical (Shanghai) Co.,Ltd.
Building 94, Lane 328, Hengyong Road, Jiading
District, Shanghai, China.

Whose single Authorized Representative:

Reliance Medical (Ireland)
Unit17, Westlink Industrial Estate, Kylemore
Road,Dublin10,Ireland

We, the manufacturer, herewith declare that the products
Sterile Wound Dressing and Sterile Eye Pad
Sterile Wound Dressing GMDN-Code: 46854
Sterile Eye Pad GMDN-Code: 11661

meet the provisions of Directive 93/42/EEC (amended by 2007/47/EC) which apply to them.

The medical device has been assigned to class I sterile according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC (amended by 2007/47/EC).

Compliance of the designated product with the Directive 93/42/EEC(amended by 2007/47/EC) has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: 15051275013
Issue date: 2020-10-09
Expiry date: 2024-05-26

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC(amended by 2007/47/EC).

Application of the abovementioned Annexes and the intervention by the Notified Body is limited to:the aspects of manufacture concerned with securing and maintaining sterile conditions. The above mentioned declaration of conformity is exclusively under the responsibility of

Reliance Medical (Shanghai) Co., Ltd

Address: Reliance Medical (Shanghai) Co.,Ltd. Building 94, Lane 328,
Hengyong Road, Jiading District, 201806 Shanghai, P.R. China.

Place,date
Shanghai 2021/08/12

Legally binding signature, Function

Jay. Jin . Quality Manager
< Miaomiaojin >