EC Declaration of Conformity

Manufacturer:
Qidong Farjoy Medical Material co., Ltd.
No.1858 Nanyuan West Rd. Economic Development Zone, Huilong Town Qidong City, 226200 P R China

whose single Authorized Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

We, the manufacturer, herewith declare that the products

Absorbent Pad

UMDNS-Code: **17428**

meet the provisions of Directive 93/42/EEC which apply to them.

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

CE 0123

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV SÜD Product Service GmbH,
Ridlerstrasse 65, 80339 MÜnchen, Germany

Certificate No.: SH19156301
Issue date: 2019-10-02
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.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Qidong Farjoy Medical Material Co., Ltd.
Address: No.1858 Nanyuan West Rd. Economic Development Zone, Huilong Town Qidong City, 226200 P R China

Qidong 2019.12.02
Place, date

Ms. Lu Yi General Manager
Legally binding signature, Function

2019.12.02

佛山朗博医疗救护用品有限公司
LONGBOW FIRST AID PRODUCTS MANUFACTORY
Tel: 86(757)81220959 **Fax:** 86(757)81019208
Web: www.chinalongbow.com **E-mail:** sales@chinalongbow.com

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: see attached product list

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

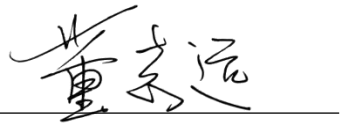
Conformity Assessment Route: Annex II Excluding 4

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: 2024.5.26
Start of CE Marking: 2021.2.2
Place, Date of Issue: Foshan City, Guangdong Province, China

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

LONGBOW 佛山朗博医疗救护用品有限公司
LONGBOW FIRST AID PRODUCTS MANUFACTORY
Tel: 86(757)81220959 **Fax:** 86(757)81019208
Web: www.chinalongbow.com **E-mail:** sales@chinalongbow.com

Product List

Product Code	Product Name
5920	Cooltherm 4g burn gel
5921	Cooltherm 5x15cm burn dressing
5922	Cooltherm 10x10cm burn dressing
5923	Cooltherm 10x40cm burn dressing
5924	Cooltherm 5x5cm burn dressing
5925	Cooltherm 30x40cm burn dressing
5926	Cooltherm 24x34cm burn dressing
5928	Cooltherm 60ml burn gel
5929	Cooltherm 120ml burn gel
391	Burnsoothe burn relief gel 3.5g
392	Burnsoothe burn relief dressing 2.5x5m
393	Burnsoothe burn relief dressing 5x15cm
394	Burnsoothe burn relief dressing 10x10cm
395	Burnsoothe burn relief dressing 20x20cm
396	Burnsoothe burn relief face mask
2399	Burnsoothe burn relief gel bottle 50ml
399	Burnsoothe burn relief gel bottle 125ml
400	Burnsoothe burn relief dressing 10x40cm
401	Burnsoothe burn relief dressing 20x45cm
402	Burnsoothe burn relief dressing 40x60cm
405	Burnsoothe Burn Relief Dressing 11.3cm x 3.7cm
407	Burnsoothe Burn Relief Dressing 13cm x 38cm
408	Burnsoothe Burn Relief Dressing 25cm x 38cm
418	Burnsoothe Burn Relief Dressing 91cm x 76cm
2391	Burnsoothe Burn Blot Sachet 3.5g x 3
2392	Burnsoothe Burn Blot Sachet 6g
2393	Burnsoothe Burn Relief Gel 160g
2395	Burnsoothe Burn Relief Gel 25g
405	Burnsoothe Burn Relief Dressing 11.3cm x 3.7cm
407	Burnsoothe Burn Relief Dressing 13cm x 38cm

Signature: 

Name: General Manager Longman Dong

Position: Foshan City, Guangdong Province, China

Compliance Report

Applicant:	Jiangsu Cureguard Glove CO., LTD
Address:	NO.65, Shenzhen Road, The Economic Development Zone, 223800 Suqian City, Jiangsu, China
Product:	Disposable Nitrile Examination Glove, Disposable Synthetic Nitrile Examination Glove, Disposable PVC Examination Glove
Type:	XS, S, M, L, XL
Product Classification:	Class I, Rule 1

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex Ⅰ, Ⅱ, Ⅲ & Ⅳ of REGULATION (EU) 2017/745

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU REGULATION have and continue to be met.

This report is not a certificate of conformity.

No. **03266**
Initial Issue Date: **08 July 2021**

Betty Bao

Signer

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 p

Plasters

GMDN-Code: 44990

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

CE 0197

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.
< Miaomiao. Jin >

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 Saline wipe

GMDN-Code:61695

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

CE 0197

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
<Miaomiao. Jin >

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

CE 0197

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.
< Miaomiao. Jin >

EN	EC Declaration of Conformity
DA	EF-overensstemmelseserklæring
DE	EC-Konformitätserklärung
ES	Declaración UE de conformidad
FI	EU-vaatimustenmukaisuusvakuutus
FR	Déclaration de conformité UE
IT	Dichiarazione di conformità CE
NL	EU-Conformiteitsverklaring
NO	EU-samsvarserklæring
PL	Deklaracja Zgodności UE
SV	EG-försäkran om överensstämmelse

RELIANCE MEDICAL
'Leading First Aid'

Reliance Medical Limited,
West Avenue, Talke, Stoke-On-Trent
Staffordshire, ST7 1TL
T +44 (0)8456 448808
F +44 (0)8456 448809
www.reliancemedical.co.uk

EN -We hereby declare that the medical device(s) specified below meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, and they are classified as a Class I medical device under rule no.1.

This declaration of conformity is issued under the sole responsibility of Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), the Manufacturer, located at the West Avenue, Talke, Stoke-On-Trent Staffordshire, England, ST7 1TL.

We have appointed Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), located at Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Ireland, as our EU Authorized Representative for these products.

This declaration applies to all batches released under the control of the technical file RMUK-TF-29 revision B.

DA - Vi erklærer hermed, at det medicinske udstyr, der er specificeret nedenfor, opfylder bestemmelserne i regulativet (EU) MDR 2017/745 for medicinsk udstyr, og at de er klassificeret som medicinsk udstyr I klasse I i henhold til regel nr. 1.

Denne overensstemmelseserklæring er udarbejdet udelukkende under Reliance Medical Ltd.'s ansvar (EUDAMED SRN GB-MF-000004799), fabrikanten, beliggende West Avenue, Talke, Stoke-on-Trent, Staffordshire, ST7 1TL, England.

Vi har udpeget Reliance Medical (Irland) (EUDAMED SRN IE-AR-000003675), beliggende Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, som vores autoriserede EU-repræsentant for disse produkter.

Denne erklæring gælder for alle batches, der er frigivet under kontrol af teknisk filnummer RMUK-TF-29 revision B.

DE - Wir erklären hiermit, dass das/die unten angegebene(n) Medizinprodukt(e) den Bestimmungen der Verordnung (EU) MDR 2017/745 für Medizinprodukte entspricht/entsprechen und nach Regel Nr. 1. als Medizinprodukt der Klasse I klassifiziert ist/sind.

Diese Konformitätserklärung wird in alleiniger Verantwortung vom Hersteller Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799) mit Sitz West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, England, ausgestellt.

Wir haben Reliance Medical (Irland) (EUDAMED SRN IE-AR-000003675) mit Sitz Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, zu unserem autorisierten EU-Vertreter für diese Produkte ernannt.

Diese Erklärung gilt für alle Chargen, die nach Kontrolle gemäß der technischen Unterlage Nr. RMUK-TF-29 Revision B freigegeben werden.

ES - Por la presente, se certifica que el(los) producto(s) sanitario(s) especificado(s) a continuación cumple(n) lo previsto en el Reglamento (UE) 2017/745 sobre los productos sanitarios y que se clasifica(n) como producto(s) sanitario(s) de la clase I conforme a la regla° 1.

La presente declaración de conformidad se emite bajo la responsabilidad exclusiva de Reliance Medical Ltd. (número de registro único de Eudamed: GB-MF-000004799), el Fabricante, con domicilio en West Avenue, Talke, Stoke-On-Trent Staffordshire, ST7 1TL, Inglaterra.

Hemos designado a Reliance Medical (Ireland) (número de registro único de Eudamed: IE-AR-000003675), con domicilio en Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irlanda, como nuestro representante autorizado en la UE para el(los) producto(s) indicado(s).

La presente declaración se aplica a todos los lotes liberados bajo el control del expediente técnico n.° RMUK-TF-29, revisión B.

FI - Vakuutamme täten, että jäljempänä kuvattu lääkinnällinen laite (laitteet) täyttää Euroopan parlamentin ja neuvoston lääkinnällisistä laitteista annetun asetuksen (EU) (MDR) 2017/745 vaatimukset, ja se on luokiteltu luokan I lääkinnälliseksi laitteeksi säännön nro 1 mukaisesti.

Tämä vaatimustenmukaisuusvakuutus on annettu valmistajan Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Englanti, yksinomaisella vastuulla.

Olemme nimittäneet Reliance Medicalin (Irlanti) (EUDAMED SRN IE-AR-000003675), Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irlanti, valtuutetuksi EU-edustajaksemme näille tuotteille.

Tämä vakuutus koskee kaikkia eriä, jotka lasketaan liikkeelle teknisen tiedoston nro RMUK-TF-29 version B vaatimusten mukaisesti.

FR - Nous attestons par la présente que le ou les dispositifs médicaux stipulés ci-dessous sont conformes au Règlement (UE) 2017/745 du Parlement européen et du Conseil relatif aux dispositifs médicaux et, le cas échéant, toute autre législation de l'Union applicable prévoyant l'établissement d'une déclaration de conformité UE, lesdits dispositifs médicaux relevant de la classe I conformément à la règle numéro 1.

Cette déclaration de conformité UE est établie sous la seule responsabilité du fabricant, Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799) établi à West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Angleterre.

Le fabricant a désigné Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675) établie à Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irlande, comme son représentant légal UE eu égard à ces produits.

Cette déclaration est valide pour tous les lots libérés conformément au dossier technique RMUK-TF-29, révision B.

IT - Con la presente si dichiara che il dispositivo medico o dispositivi medici sotto indicati rispondono alle disposizioni del Regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio relativo ai dispositivi medici, e rientrano nella Classe I dei dispositivi medici a norma della regola N. 1.

La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva di Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), il fabbricante, con sede in West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Inghilterra.

Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), con sede in Unit 17, Westlink Industrial Estate, Kylemore Road, Dublino 10, Irlanda, è stata nominata come nostro mandatario per questi prodotti.

Questa dichiarazione si applica a tutti i lotti rilasciati sotto il controllo del fascicolo tecnico N. RMUK-TF-29 revisione B.

NL - Wij verklaren hierbij dat het/de medisch hulpmiddel(en) zoals hieronder aangegeven voldoet/voldoen aan de bepaling van Verordening (EU) MDR 2017/745 voor medische hulpmiddelen en is/zijn geclassificeerd als Klasse I medisch hulpmiddel regel nr. 1.

Deze conformiteitsverklaring wordt uitgegeven onder de uitsluitende verantwoordelijkheid van Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), de fabrikant, gevestigd op het adres West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Engeland.

Wij hebben Reliance Medical (Ierland) (EUDAMED SRN IE-AR-000003675), gevestigd op het adres Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Ierland, benoemd als onze gemachtigde in de EU voor deze producten.

Deze verklaring is van toepassing op alle batches vrijgegeven onder de controle van technisch dossier RMUK-TF-29 revisie B.

NO - Vi erklærer herved at det medisinske utstyret spesifisert nedenfor oppfyller kravene i Europaparlaments- og rådsforordning (EU) nr. 2017/745 om medisinsk utstyr (MDR), og at det er klassifisert som medisinsk utstyr i klasse I i henhold til regel nr. 1.

Denne samsvarserklæringen er utstedt på eneansvar av produsenten Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), med adresse West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, England.

Vi har oppnevnt Reliance Medical (Irland) (EUDAMED SRN IE-AR-000003675), med adresse Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, som vår autoriserte EU-representant for disse produktene.

Denne erklæringen gjelder for alle partier som frigis under teknisk filnr. RMUK-TF-29, revidert utgave B.

PL - Oświadczamy, że wyroby medyczne, których dotyczy ta deklaracja są zgodne z Rozporządzeniem Parlamentu Europejskiego i Rady (UE) 2017/745 oraz w stosownych przypadkach z wszystkimi innymi odpowiednimi przepisami unijnymi, które przewidują wydanie deklaracji zgodności UE.

Poniższe wyroby medyczne należą do klasy I oraz podlegają regule 1.

Niniejsza deklaracja zgodności UE, została wydana na wyłączną odpowiedzialność producenta, Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), z siedzibą przy West Avenue, Talke, Stoke-On-Trent Staffordshire, England, ST7 1TL.

Oświadczamy, że Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), z siedzibą w Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Ireland, jest upoważniony do występowania w imieniu Reliance Medical z siedzibą w Wielkiej Brytanii, w zakresie określonych zadań w odniesieniu do obowiązków producenta wynikających z Rozporządzenia (UE) 2017/745.

Niniejsza deklaracja dotyczy wszystkich partii produktu wykonanych pod nadzorem Dokumentacji Technicznej RMUK-TF-29 Rev B.

SV - Vi intygar härmed att de medicintekniska produkterna som specificeras nedan uppfyller bestämmelserna i förordning (EU) MDR 2017/745 om medicintekniska produkter, och de klassificeras som medicintekniska produkter i klass I enligt regel nr. 1.

Denna försäkran om överensstämmelse utfärdas på eget ansvar av Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), tillverkaren, med adress West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, England.

Vi har utsett Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), med adress Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, till vår auktoriserade EU-representant för dessa produkter.

Denna försäkran gäller för alla partier som släpps under kontroll av tekniskt filnummer RMUK-TF-29 revision B.

EN - Signed:
Person Responsible for Regulatory Compliance
On behalf of Reliance Medical Ltd

ES - Fdo.:
Responsable de Cumplimiento Normativo
Por: Reliance Medical Ltd
IT - Firmato:
Persona responsabile del rispetto della normativa
Per conto di Reliance Medical Ltd
PL - Podpisano:
Stanowisko:
Z upoważnienia:

DA - Underskrevet:
Person, der er ansvarlig for overholdelse af reguleringen
På vegne af Reliance Medical Ltd

FI - Allekirjoittaja:
säännösten noudattamisesta vastaava henkilö
Reliance Medical Ltd:n puolesta
NL - Ondertekend:
Persoon verantwoordelijk voor naleving van de regelgeving namens Reliance Medical Ltd
SV - Underskrift:
Person ansvarig för regelefterlevnad
på uppdrag av Reliance Medical Ltd

DE - Unterschrift:
Verantwortliche Person für die Einhaltung von Vorschriften Im Namen der Reliance Medical Ltd

FR - Signature :
Le responsable de la conformité règlementaire
Pour le compte de Reliance Medical Ltd
NO - Signert:
Person med ansvar for overholdelse av regelverk
på vegne av Reliance Medical Ltd

Monika Bogucka

EN - Place and Date:
ES - Lugar y fecha:
IT - Luogo e data:
PL - Data i miejsce:

DA - Sted og dato:
FI - Paikka ja aika:
NL - Plaats en datum:
SV - Ort och datum:

DE - Ort und Datum:
FR - Lieu et date de délivrance :
NO - Sted og dato:

26.05.2021
Talke, Stoke on Trent

Product REF	Basic UDI-DI	UDI-DI	Product Description
411	506013188TF2942	05060131884110	Single Use Triangular Bandage 90x127cm
413	506013188TF2942	05060131884134	Calico Triangular Bandage 90x127cm
415	506013188TF2942	05060131884158	Triangular Bandage 95x135cm hemmed
420	506013188TF2942	05060131884202	Single Use Triangular Bandage Boxed 90cm x 127cm
941	506013188TF2942	05060131889412	Single Use Triangular Bandage Blue 90 x127cm
9494-5	506013188TF2942	05060738579044	Businesscare Triangular Bandage Box of 2
C090	506013188TF2942	05060738578832	Lifemarque Triangular Bandage Cotton 90cm x 90cm x 127cm
X1180	506013188TF2942	05060738578900	BCB Calico Triangular Bandage 90cm x 127cm
X1198	506013188TF2942	05060738578917	BCB Non-woven Triangular Bandage 90cm x 127cm
X1335	506013188TF2942	05060497998834	Red Cross NZ Single Use Triangular Bandage 90 x 127cm
X1655	506013188TF2942	05060186994482	Arasca Single use Triangular Bandage 90 x 127cm (411-AR)
X1926	506013188TF2942	05060131889412	Ash Medical single use triangular bandage 90 x 127cm
X2925	506013188TF2942	05060497993662	ISS Single Use Triangular Bandage 90 x 127cm
X2926	506013188TF2942	05060497993679	Single Use Triangular Bandage 90 x 127cm - Box of 2
X4412	506013188TF2942	05060497997264	Single Use Calico Triangular Bandage (113cm x 113xm x 160cm)
X4413	506013188TF2942	05060497993396	Single Use Triangular Bandage 30g 90cm x 127cm
X7411	506013188TF2942	05060186996042	Single use triangular bandage 90 x 127cm - Pack of 12 (FST69022)
X7415	506013188TF2942	05060738578993	St Andrews Calico triangular bandage 95 x 135cm hemmed

EN	**EC Declaration of Conformity**
DA	**EF-overensstemmelseserklæring**
DE	**EC-Konformitätserklärung**
ES	**Declaración UE de conformidad**
FI	**EU-vaatimustenmukaisuusvakuutus**
FR	**Déclaration de conformité UE**
IT	**Dichiarazione di conformità CE**
NL	**EU-Conformiteitsverklaring**
NO	**EU-samsvarserklæring**
PL	**Deklaracja Zgodności UE**
SV	**EG-försäkran om överensstämmelse**

RELIANCE MEDICAL
'Leading First Aid'

Reliance Medical Limited,
West Avenue, Talke, Stoke-On-Trent
Staffordshire, ST7 1TL
T +44 (0)8456 448808
F +44 (0)8456 448809
www.reliancemedical.co.uk

EN -We hereby declare that the medical device(s) specified below meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, and they are classified as a Class I medical device under rule no.1.

This declaration of conformity is issued under the sole responsibility of Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), the Manufacturer, located at the West Avenue, Talke, Stoke-On-Trent Staffordshire, England, ST7 1TL.

We have appointed Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), located at Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Ireland, as our EU Authorized Representative for these products.

This declaration applies to all batches released under the control of the technical file RMUK-TF-33 revision B.

DA - Vi erklærer hermed, at det medicinske udstyr, der er specificeret nedenfor, opfylder bestemmelserne i regulativet (EU) MDR 2017/745 for medicinsk udstyr, og at de er klassificeret som medicinsk udstyr i klasse I i henhold til regel nr. 1.

Denne overensstemmelseserklæring er udarbejdet udelukkende under Reliance Medical Ltd.'s ansvar (EUDAMED SRN GB-MF-000004799), fabrikanten, beliggende West Avenue, Talke, Stoke-on-Trent, Staffordshire, ST7 1TL, England.

Vi har udpeget Reliance Medical (Irland) (EUDAMED SRN IE-AR-000003675), beliggende Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, som vores autoriserede EU-repræsentant for disse produkter.

Denne erklæring gælder for alle batches, der er frigivet under kontrol af teknisk filnummer RMUK-TF-33 revision B.

DE - Wir erklären hiermit, dass das/die unten angegebene(n) Medizinprodukt(e) den Bestimmungen der Verordnung (EU) MDR 2017/745 für Medizinprodukte entspricht/entsprechen und nach Regel Nr. 1. als Medizinprodukt der Klasse I klassifiziert ist/sind.

Diese Konformitätserklärung wird in alleiniger Verantwortung vom Hersteller Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799) mit Sitz West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, England, ausgestellt.

Wir haben Reliance Medical (Irland) (EUDAMED SRN IE-AR-000003675) mit Sitz Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, zu unserem autorisierten EU-Vertreter für diese Produkte ernannt.

Diese Erklärung gilt für alle Chargen, die nach Kontrolle gemäß der technischen Unterlage Nr. RMUK-TF-33 Revision B freigegeben werden.

ES - Por la presente, se certifica que el(los) producto(s) sanitario(s) especificado(s) a continuación cumple(n) lo previsto en el Reglamento (UE) 2017/745 sobre los productos sanitarios y que se clasifica(n) como producto(s) sanitario(s) de la clase I conforme a la regla* 1.

La presente declaración de conformidad se emite bajo la responsabilidad exclusiva de Reliance Medical Ltd. (número de registro único de Eudamed: GB-MF-000004799), el Fabricante, con domicilio en West Avenue, Talke, Stoke-On-Trent Staffordshire, ST7 1TL, Inglaterra.

Hemos designado a Reliance Medical (Ireland) (número de registro único de Eudamed: IE-AR-000003675), con domicilio en Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irlanda, como nuestro representante autorizado en la UE para el(los) producto(s) indicado(s).

La presente declaración se aplica a todos los lotes liberados bajo el control del expediente técnico n.° RMUK-TF-33, revisión B.

FI - Vakuutamme täten, että jäljempänä kuvattu lääkinnällinen laite (laitteet) täyttää Euroopan parlamentin ja neuvoston lääkinnällisistä laitteista annetun asetuksen (EU) (MDR) 2017/745 vaatimukset, ja se on luokiteltu luokan I lääkinnälliseksi laitteeksi säännön nro 1 mukaisesti.

Tämä vaatimustenmukaisuusvakuutus on annettu valmistajan Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Englanti, yksinomaisella vastuulla.

Olemme nimittäneet Reliance Medicalin (Irlanti) (EUDAMED SRN IE-AR-000003675), Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irlanti, valtuutetuksi EU-edustajaksemme näille tuotteille.

Tämä vakuutus koskee kaikkia eriä, jotka lasketaan liikkeelle teknisen tiedoston nro RMUK-TF-33 version B vaatimusten mukaisesti.

FR - Nous attestons par la présente que le ou les dispositifs médicaux stipulés ci-dessous sont conformes au Règlement (UE) 2017/745 du Parlement européen et du Conseil relatif aux dispositifs médicaux et, le cas échéant, toute autre législation de l'Union applicable prévoyant l'établissement d'une déclaration de conformité UE, lesdits dispositifs médicaux relevant de la classe I conformément à la règle numéro 1.

Cette déclaration de conformité UE est établie sous la seule responsabilité du fabricant, Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799) établi à West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Angleterre.

Le fabricant a désigné Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675) établie à Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irlande, comme son représentant légal UE eu égard à ces produits.

Cette déclaration est valide pour tous les lots libérés conformément au dossier technique RMUK-TF-33, révision B.

IT - Con la presente si dichiara che il dispositivo medico o dispositivi medici sotto indicati rispondono alle disposizioni del Regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio relativo ai dispositivi medici, e rientrano nella Classe I dei dispositivi medici a norma della regola N. 1.

La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva di Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), il fabbricante, con sede in West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Inghilterra.

Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), con sede in Unit 17, Westlink Industrial Estate, Kylemore Road, Dublino 10, Irlanda, è stata nominata come nostro mandatario per questi prodotti.

Questa dichiarazione si applica a tutti i lotti rilasciati sotto il controllo del fascicolo tecnico N. RMUK-TF-33 revisione B.

NL - Wij verklaren hierbij dat het/de medisch hulpmiddel(en) zoals hieronder aangegeven voldoet/voldoen aan de bepaling van Verordening (EU) MDR 2017/745 voor medische hulpmiddelen en is/zijn geclassificeerd als Klasse I medisch hulpmiddel regel nr. 1.

Deze conformiteitsverklaring wordt uitgegeven onder de uitsluitende verantwoordelijkheid van Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), de fabrikant, gevestigd op het adres West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, Engeland.

Wij hebben Reliance Medical (Ierland) (EUDAMED SRN IE-AR-000003675), gevestigd op het adres Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Ierland, benoemd als onze gemachtigde in de EU voor deze producten.

Deze verklaring is van toepassing op alle batches vrijgegeven onder de controle van technisch dossier RMUK-TF-33 revisie B.

NO - Vi erklærer herved at det medisinske utstyret spesifisert nedenfor oppfyller kravene i Europaparlaments- og rådsforordning (EU) nr. 2017/745 om medisinsk utstyr (MDR), og at det er klassifisert som medisinsk utstyr i klasse I i henhold til regel nr. 1.

Denne samsvarserklæringen er utstedt på eneansvar av produsenten Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), med adresse West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, England.

Vi har oppnevnt Reliance Medical (Irland) (EUDAMED SRN IE-AR-000003675), med adresse Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, som vår autoriserte EU-representant for disse produktene.

Denne erklæringen gjelder for alle partier som frigis under teknisk filnr. RMUK-TF-33, revidert utgave B.

PL - Oświadczamy, że wyroby medyczne, których dotyczy ta deklaracja są zgodne z Rozporządzeniem Parlamentu Europejskiego i Rady (UE) 2017/745 oraz w stosownych przypadkach z wszystkimi innymi odpowiednimi przepisami unijnymi, które przewidują wydanie deklaracji zgodności UE.

Poniższe wyroby medyczne należą do klasy I oraz podlegają regule 1.

Niniejsza deklaracja zgodności UE, została wydana na wyłączną odpowiedzialność producenta, Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), z siedzibą przy West Avenue, Talke, Stoke-On-Trent Staffordshire, England, ST7 1TL.

Oświadczamy, że Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), z siedzibą w Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Ireland, jest upoważniony do występowania w imieniu Reliance Medical z siedzibą w Wielkiej Brytanii, w zakresie określonych zadań w odniesieniu do obowiązków producenta wynikających z Rozporządzenia (UE) 2017/745.

Niniejsza deklaracja dotyczy wszystkich partii produktu wykonanych pod nadzorem Dokumentacji Technicznej RMUK-TF-33 Rev B.

SV - Vi intygar härmed att de medicintekniska produktema som specificeras nedan uppfyller bestämmelserna i förordning (EU) MDR 2017/745 om medicintekniska produkter, och de klassificeras som medicintekniska produkter i klass I enligt regel nr. 1.

Denna försäkran om överensstämmelse utfärdas på eget ansvar av Reliance Medical Ltd. (EUDAMED SRN GB-MF-000004799), tillverkaren, med adress West Avenue, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, England.

Vi har utsett Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), med adress Unit 17, Westlink Industrial Estate, Kylemore Road, Dublin 10, Irland, till vår auktoriserade EU-representant för dessa produkter.

Denna försäkran gäller för alla partier som släpps under kontroll av tekniskt filnummer RMUK-TF-33 revision B.

EN - Signed:
Person Responsible for Regulatory Compliance
On behalf of Reliance Medical Ltd

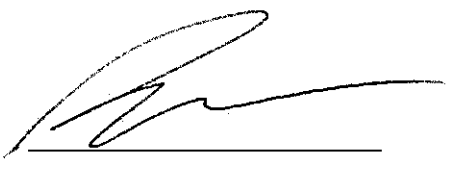
DA - Underskrevet:
Person, der er ansvarlig for overholdelse af reguleringen
På vegne af Reliance Medical Ltd

DE - Unterschrift:
Verantwortliche Person für die Einhaltung von Vorschriften im Namen der Reliance Medical Ltd

ES - Fdo.:
Responsable de Cumplimiento Normativo
Por: Reliance Medical Ltd
IT - Firmato:
Persona responsabile del rispetto della normativa
Per conto di Reliance Medical Ltd
PL - Podpisano:
Stanowisko:
Z upoważnienia:

FI - Allekirjoittaja:
säännösten noudattamisesta vastaava henkilö
Reliance Medical Ltd:n puolesta
NL - Ondertekend:
Persoon verantwoordelijk voor naleving van de regelgeving namens Reliance Medical Ltd
SV - Underskrift:
Person ansvarig för regelefterlevnad
på uppdrag av Reliance Medical Ltd

FR - Signature :
Le responsable de la conformité règlementaire
Pour le compte de Reliance Medical Ltd
NO - Signert:
Person med ansvar for overholdelse av regelverk
på vegne av Reliance Medical Ltd



EN - Place and Date:
ES - Lugar y fecha:
IT - Luogo e data:
PL - Data i miejsce:

DA - Sted og dato:
FI - Paikka ja aika:
NL - Plaats en datum:
SV - Ort och datum:

DE - Ort und Datum:
FR - Lieu et date de délivrance :
NO - Sted og dato:

Talke,
26 May 2021

Product REF	Basic UDI-DI	UDI-DI	Product Description
760	506013188TF333R	05060131887609	Foil Blanket Adult Size
761	506013188TF333R	05060131887616	Foil Blanket Children Size
764	506013188TF333R	05060131887647	Foil Blanket Adult Size Boxed - 130cm x 210cm
94271	506013188TF333R	05060738579075	Businesscare Foil Blanket (Boxed)
B300	506013188TF333R	05060186997186	Evaq8 Emergency Foil Blanket
B315	506013188TF333R	05060176883925	Evaq8 Emergency Foil Blanket Gold/Silver
LP760	506013188TF333R	05060497997875	Lewis-Plast Foil Blanket 130cm x 210cm
X1380	506013188TF333R	05060497998933	Red Cross NZ Foil Blanket Adult Size - 130cm x 210cm
X7325	506013188TF333R	05060738579020	St Andrews foil blanket adult size
X7760	506013188TF333R	05060186995700	Foil Survival Blanket Adult - Pack of 5 (FST69009)
X9450	506013188TF333R	05060497990678	Bunzl Foil Blankets - Pack of 5 - MED6200FL