# 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: Emergency Burn Dressing
Model: Attachment 1
GMDN code: 47694

Classification (MDD, Annex Ⅱ): 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. Longbow First Aid Products Manufactory is exclusively responsible for th Doc.

## DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices.

| | |
|---|---|
| Notified Body: | TÜV SÜD Product Service GmbH |
| Address: | Ridlerstr. 65, 80339 MÜnchen, Germany |
| Identification number: | CE 0123 |
| (EC) Certificate(s): | G1 060834 0025 Rev.00 |
| 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
Date 07/11/2020

Attachment I

| |
|---|
| Burnsoothe 3.5g |
| Burnsoothe 2.5x5cm |
| Burnsoothe 5x15cm |
| Burnsoothe 10x10cm |
| Burnsoothe 20x20cm |
| Burnsoothe Face Mask 30x40cm |
| Burnsoothe 50ml |
| Burnsoothe 125ml |
| Burnsoothe 10x40cm |
| Burnsoothe 20x45cm |
| Burnsoothe 40x60cm |

Signature:

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

# 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**
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the aspects of manufacture concerned with securing and maintaining sterile conditions.

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**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 >

TÜVRheinland®

# EC Certificate

## Directive 93/42/EEC Annex V
## Production Quality Assurance
## Medical Devices

**Registration No.:** DD 60150860 0001

**Report No.:** 15051275 013

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

**Products:** Medical Devices

(see attachment for products included)

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-10-09

**Date:** 2020-10-09

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1 Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** DD 60150860 0001
**Report No.:** 15051275 013

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

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile Wound Dressings
- Sterile Eye Pads
- Sterile Saline Wipes
- Plasters

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

Date: 2020-10-09

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-20 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-20 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-20 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-20, 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-20 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-20, 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-20 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-20 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-20, 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-20 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-20 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

Paulina Boguchwa

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 |
|---|---|---|---|
| 423 | 506013188TF203G | 05060131884233 | Reliwow Bandage 7.5cm x 5m |
| 424 | 506013188TF203G | 05060131884240 | Reliwow Bandage 10cm x 5m |
| 431 | 506013188TF203G | 05060131884318 | Reliform Conforming Bandage 5cm x 4m |
| 432 | 506013188TF203G | 05060131884325 | Reliform Conforming Bandage 7.5cm x 4m |
| 433 | 506013188TF203G | 05060131884332 | Reliform Conforming Bandage 10cm x 4m |
| 434 | 506013188TF203G | 05060131884349 | Reliform Conforming Bandage 15cm x 4m |
| 441 | 506013188TF203G | 05060131884417 | Relicrepe crepe bandage BP 5cm x 4.5m |
| 442 | 506013188TF203G | 05060131884424 | Relicrepe crepe bandage BP 7.5cm x 4.5m |
| 443 | 506013188TF203G | 05060131884431 | Relicrepe crepe bandage BP 10cm x 4.5m |
| 444 | 506013188TF203G | 05060131884448 | Relicrepe crepe bandage BP 15cm x 4.5m |
| 461 | 506013188TF5747 | 05060131884615 | Religrip Elasticated Tubular Bandage 4.5cm x 10m |
| 462 | 506013188TF5747 | 05060131884622 | Religrip Elasticated Tubular Bandage 6.25cm x 10m |
| 463 | 506013188TF5747 | 05060131884639 | Religrip Elasticated Tubular Bandage 6.75cm x 10m |
| 464 | 506013188TF5747 | 05060131884646 | Religrip Elasticated Tubular Bandage 7.5cm x 10m |
| 465 | 506013188TF5747 | 05060131884653 | Religrip Elasticated Tubular Bandage 8.75cm x 10m |
| 466 | 506013188TF5747 | 05060131884660 | Religrip Elasticated Tubular Bandage 10cm x 10m |
| 467 | 506013188TF5747 | 05060131884677 | Religrip Elasticated Tubular Bandage 12cm x 10m |
| 471 | 506013188TF5747 | 05060131884714 | Religrip Elasticated Tubular Bandage size A 1m |
| 472 | 506013188TF5747 | 05060131884721 | Religrip Elasticated Tubular Bandage size B 1m |
| 473 | 506013188TF5747 | 5060131884738 | Religrip Elasticated Tubular Bandage size C 1m |
| 474 | 506013188TF5747 | 05060131884745 | Religrip Elasticated Tubular Bandage size D 1m |
| 475 | 506013188TF5747 | 05060131884752 | Religrip Elasticated Tubular Bandage size E 1m |
| 476 | 506013188TF5747 | 05060131884769 | Religrip Elasticated Tubular Bandage size F 1m |
| 477 | 506013188TF5747 | 05060131884776 | Religrip Elasticated Tubular Bandage size G 1m |
| 481 | 506013188TF5747 | 05060131884813 | Religauze tubular gauze size 01 20m |
| 482 | 506013188TF5747 | 05060131884820 | Religauze tubular gauze size 12 20m |
| 703 | 506013188TF203G | 05060131887036 | Relicrepe Crepe Bandage HQ 5.0cm x 4m |
| 803 | 506013188TF203G | 05060131888033 | Relicrepe Crepe Bandage HQ 7.5cm x 4m |
| 804 | 506013188TF203G | 05060131888040 | Relicrepe Crepe Bandage HQ 10cm x 4m |
| 808 | 506013188TF203G | 05060131888088 | Relicrepe Crepe Bandage HQ 15cm x 4m |
| 1803 | 506013188TF203G | 05060186996233 | Relicrepe Blue Crepe Bandage HQ 7.5cm x 4m |
| 1811 | 506013188TF203G | 05060738578023 | Proteqt Crepe Bandage BP 7.5cm x 4.5m |
| 1812 | 506013188TF203G | 05060738578030 | Proteqt Crepe Bandage BP 10cm x 4.5m |
| 2040 | 506013188TF203G | 05060497997721 | Reliwow Bandage BP Individually Wrapped 2.5cm x 5m |
| 2041 | 506013188TF203G | 05060497997738 | Single Reliwow bandage individually wrapped 5cm x 5m |
| 2042 | 506013188TF203G | 05060497997745 | Reliwow bandage individually wrapped 7.5cm x 5m |
| 2052 | 506013188TF203G | 05060497997752 | Reliwow bandage individually wrapped 10cm x 5m |
| 2432 | 506013188TF203G | 05060186990699 | Conforming Bandage (Blue) 7.5cm x 4m |
| 2435 | 506013188TF203G | 05060186991191 | Proteqt Cohesive Bandage Blue 5cm x 4.5m |
| 2440 | 506013188TF203G | 05060738571444 | Reliform Boxed Conforming Bandage 7.5cm x 4m |
| 2450 | 506013188TF203G | 05060186991139 | Proteqt Conforming Bandage 7.5cm x 4m |
| 3818 | 506013188TF203G | 05025503125420 | Lewis-Plast Conforming Bandage 10cm X 4m Stretched |
| 81414 | 506013188TF203G | 05060147330083 | Medikit Conforming bandage |
| 81416 | 506013188TF203G | 05060147330090 | Medikit Conforming bandage |
| 81418 | 506013188TF203G | 05060147330106 | Medikit Conforming bandage |
| C040 | 506013188TF203G | 05060738578764 | Lifemarque Cotton Crepe Bandage 5cm x 4.5m |
| C050 | 506013188TF203G | 05060738578771 | Lifemarque Cotton Crepe Bandage 7.5cm x 4.5m |
| C150 | 506013188TF203G | 05060738578788 | Lifemarque White Open Wove Bandage 7.5cm x 5m |
| X1183 | 506013188TF203G | 05060738578887 | BCB Conforming Bandage 7.5cm x 4m |
| X1356 | 506013188TF203G | 05060497998872 | Red Cross NZ Conforming Bandage 7.5cm x 4m |
| X1360 | 506013188TF203G | 05060497998889 | Red Cross NZ Crepe Bandage BP 7.5cm x 4.5m |
| X1362 | 506013188TF203G | 05060738576784 | Red Cross NZ Crepe Bandage HQ 7.5cm x 4m |
| X1585 | 506013188TF203G | 05060738577897 | Red Cross NZ Conforming Bandage 7.5cm x 4m - Boxed |
| X1640 | 506013188TF203G | 05060186998633 | Arasca Conforming Bandage 15cm x 4m (434-AR) |
| X1651 | 506013188TF203G | 05060186999005 | Arasca Crepe Bandage HQ 15cm x 4m |
| X1652 | 506013188TF203G | 05060186994505 | Arasca Crepe Bandage HQ 10cm x 4m (804-AR) |
| X1653 | 506013188TF203G | 05060186998992 | Arasca Crepe Bandage HQ 7.5cm x 4m |
| X1654 | 506013188TF203G | 05060186994499 | Arasca Crepe Bandage HQ 5.0cm x 4m (703-AR) |
| X1656 | 506013188TF203G | 05060186998647 | Arasca Conforming Bandage 10cm x 4m |
| X1659 | 506013188TF203G | 05060186994451 | Arasca Conforming bandage 7.5cm x 4m (432-AR) |
| X1660 | 506013188TF203G | 05060186994444 | Arasca Conforming Bandage 5cm x 4m (431-AR) |
| X7316 | 506013188TF203G | 05060738578955 | St Andrews crepe bandage BP 5cm x 4.5m |
| X7317 | 506013188TF203G | 05060738578962 | St Andrews crepe bandage BP 7.5cm x 4.5m |
| X7320 | 506013188TF203G | 05060738578979 | St Andrews conforming bandage 5cm x 4m |
| X7323 | 506013188TF203G | 05060738578986 | St Andrews conforming bandage 10cm x 4m |

| | |
|---|---|
| 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
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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-27 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-27 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-27 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-27, 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-27 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-27, 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-27 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-27 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-27, 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-27 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-27 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 réglementaire
Pour le compte de Reliance Medical Ltd
NO - Signert:
Person med ansvar for overholdelse av regelverk
på vegne av Reliance Medical Ltd

Claudia Boqueda

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

Stoke on Trent

| Product REF | Basic UDI-DI | UDI-DI | Product Description |
|---|---|---|---|
| 579 | 506013188TF273W | 05060131885797 | Microporous tape 1.25cm x 1m |
| 603 | 506013188TF273W | 05060131886039 | Zinc Oxide Tape 1.25cm x 5m |
| 604 | 506013188TF273W | 05060131886046 | Zinc Oxide Tape 2.5cm x 5m |
| 605 | 506013188TF273W | 05060131886053 | Zinc Oxide Tape 5cm x 5m |
| 608 | 506013188TF273W | 05032483003198 | ProteQt Fabric Strapping Tape Cap & Spool 2.5cm x 1.5m |
| 609 | 506013188TF273W | 05060131886091 | Relitape Premier Sports Tape - 3.8cm x 13.7m |
| 610 | 506013188TF273W | 05060131886107 | Relitape washproof pink tape 2.5cm x 5m |
| 611 | 506013188TF273W | 05060131886114 | Washproof blue tape 2.5cm x 5m |
| 612 | 506013188TF273W | 05060131886121 | Relitape fabric elastic pink tape 2.5cm x 4.5m |
| 613 | 506013188TF273W | 05060131886138 | Zinc Oxide Tape 1.25cm x 10m |
| 614 | 506013188TF273W | 05060131886145 | Zinc Oxide Tape 2.5cm x 10m |
| 615 | 506013188TF273W | 05060131886152 | Zinc Oxide Tape 5cm x 10m |
| 616 | 506013188TF273W | 05060131886169 | Microporous tape 1.25cm x 10m |
| 617 | 506013188TF273W | 05060131886176 | Microporous tape 2.5cm x 10m |
| 618 | 506013188TF273W | 05060131886183 | Relitape silk tape 1.25cm x 10m |
| 619 | 506013188TF273W | 05060131886190 | Relitape silk tape 2.5cm x 10m |
| 620 | 506013188TF273W | 05060131886206 | Relifix adhesive dressing sheet 2.5cm x 10m |
| 621 | 506013188TF273W | 05060131886213 | Relifix adhesive dressing sheet 5cm x 10m |
| 622 | 506013188TF273W | 05060131886220 | Relifix adhesive dressing sheet 10cm x 10m |
| 623 | 506013188TF273W | 05060131886237 | Relifix adhesive dressing sheet 15cm x 10m |
| 625 | 506013188TF273W | 05060131886251 | Microporous tape 5cm x 10m |
| 632 | 506013188TF273W | 05060131886329 | Transparent perforated easy tear tape 2.5cm x 9.14m |
| 641 | 506013188TF273W | 05060131886411 | Microporous tape 2.5cm x 5m with dispenser |
| 642 | 506013188TF273W | 05032483000227 | Microporous Surgical Tape & Dispenser 2.5cm x 10m |
| 643 | 506013188TF273W | 05032483003167 | Proteqt Microporous Tape Cap & Spool 2.5cm x 5m |
| 650 | 506013188TF273W | 05060131886503 | Relitape Zinc Oxide Tape 7.5cm x 5m |
| 685 | 506013188TF273W | 05060131886855 | Microporous tape 2.5cm x 5m |
| 2685 | 506013188TF273W | 05060738571451 | Relitape Boxed Microporous Tape 2.5cm x 5m |
| 94257 | 506013188TF273W | 05060738579037 | Businesscare Microporous Tape 2.5cm x 10m |
| C170 | 506013188TF273W | 05060738578795 | Lifemarque Zinc Oxide Tape 2.5cm x 2m |
| C180 | 506013188TF273W | 05060738578801 | Lifemarque Zinc Oxide Tape 1.25cm x 5m |
| C350 | 506013188TF273W | 05060738578818 | Lifemarque Microporous Tape 1.25cm x 5m |
| C365 | 506013188TF273W | 05060738578825 | Lifemarque Microporous Tape 2.5cm x 5m |
| X1199 | 506013188TF273W | 05060738578894 | BCB Zinc Oxide Tape 1.25cm x 5m White |
| X1587 | 506013188TF273W | 05060738577927 | Red Cross NZ Microporous Tape 2.5cm x 5m - Boxed |
| X1591 | 506013188TF273W | 05060738577989 | Red Cross NZ Microporous Tape 2.5cm x 5m |
| X5662 | 506013188TF273W | 05010204264424 | Tesco Fabric Strapping Tape 2.5cm x 4.5m |
| X7854 | 506013188TF273W | 05060497998179 | Mini First Aid Microporous Tape 1.25cm x 10m |

| | |
|---|---|
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| 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 |


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**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 |

Variable information: Do not send this page

| | |
|---|---|
| Device Class | I |
| MDR Classification Rule | 5 |
| Technical File Reference | RMUK-TF-30 |
| Technical File Revision | B |

| | |
|---|---|
| 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.5.

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-30 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. 5.

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-30 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. 5. 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-30 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° 5.

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-30, 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 5 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-30 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 5.

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-30, 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. 5.

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-30 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. 5.

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-30 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. 5.

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-30, 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 5.

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-30 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. 5.

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-30 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

Claudia Boguslaa

**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, Stoke on Trent
26.05.2021

| Product REF | Basic UDI-DI | UDI-DI | Product Description |
|---|---|---|---|
| 022 | 506013188TF303K | 05060131880228 | Vinyl Powder-Free Gloves Box of 100 |
| 023 | 506013188TF303K | 05060131880235 | Vinyl Powder-Free Gloves Box of 100 |
| 024 | 506013188TF303K | 05060131880242 | Vinyl Powder-Free Gloves Box of 100 |
| 025 | 506013188TF303K | 05060131880259 | Vinyl Powder-Free Gloves Box of 100 |
| 029 | 506013188TF303K | 05060131880297 | Religlove vinyl powder-free medium single pair |
| 049 | 506013188TF303K | 05060131880495 | Religlove latex powder-free medium/large single pair |
| 042 | 506013188TF303K | 05060131880426 | Latex Powder-Free Gloves Box of 100 |
| 043 | 506013188TF303K | 05060131880433 | Latex Powder-Free Gloves Box of 100 |
| 044 | 506013188TF303K | 05060131880440 | Latex Powder-Free Gloves Box of 100 |
| 045 | 506013188TF303K | 05060131880457 | Latex Powder-Free Gloves Box of 100 |
| 059 | 506013188TF303K | 05060131880594 | Religlove nitrile powder-free medium/large single pair |
| 052 | 506013188TF303K | 05060131880525 | Nitrile Powder-Free Gloves Box of 100 |
| 053 | 506013188TF303K | 05060131880532 | Nitrile Powder-Free Gloves Box of 100 |
| 054 | 506013188TF303K | 05060131880549 | Nitrile Powder-Free Gloves Box of 100 |
| 055 | 506013188TF303K | 05060131880556 | Nitrile Powder-Free Gloves Box of 100 |
| 2949 | 506013188TF303K | 05060497994218 | Religlove Nitrile Gloves Boxed 12 Pairs |
| 705 | 506013188TF303K | 05060131887050 | Retail cotton gloves white |
| 706 | 506013188TF303K | 05060131887067 | Retail cotton gloves white |
| 707 | 506013188TF303K | 05060131887074 | Retail cotton gloves white |
| 947 | 506013188TF303K | 05060131889474 | Nitrile Gloves boxed 6 pairs (for BS8599-1 kits) |
| 949 | 506013188TF303K | 05060131889498 | Nitrile Gloves boxed 9 pairs (for BS8599-1 kits) |
| 94675 | 506013188TF303K | 05060738579051 | Businesscare Nitrile Gloves Pairs |
| C100 | 506013188TF303K | 05060738578849 | Lifemarque Nitrile Gloves Large (Pair) |
| LP947 | 506013188TF303K | 05060497997899 | Nitrile Gloves Pack of 12 (6 Pairs) |
| LP949 | 506013188TF303K | 05060497997929 | Nitrile Gloves Pack of 18 (9 Pairs) |
| X1395 | 506013188TF303K | 05060497998957 | Red Cross NZ Nitrile Gloves Boxed 6 Pairs |
| X1396 | 506013188TF303K | 05060497999046 | Red Cross NZ Nitrile Gloves Powder Free - Pair |
| X1568 | 506013188TF303K | 05060497999640 | Red Cross NZ Nitrile Gloves Boxed 9 Pairs |
| X1670 | 506013188TF303K | 05060186994352 | Arasca Nitrile Powder-free Medium gloves - single pair (059-AR-M) |
| X1671 | 506013188TF303K | 05060497997011 | Arasca Nitrile Powder-free Large Gloves - single pair (059-AR-L) |
| X3022 | 506013188TF303K | 05060738579105 | Religlove vinyl powder-free small - pack of 20 (GLO63906SML) |
| X3023 | 506013188TF303K | 05060186997155 | Religlove vinyl powder-free medium - pack of 20 (GLO63906MED) |
| X3024 | 506013188TF303K | 05060738579112 | Religlove vinyl powder-free large- pack of 20 (GLO63906LRG) |
| X3025 | 506013188TF303K | 05060738579129 | Religlove vinyl powder-free extra large - pack of 20 (GLO63906XL) |

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


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**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-32 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-32 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-32 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-32, 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 laskетaan liikkeelle teknisen tiedoston nro RMUK-TF-32 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-32, 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-32 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, England.

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-32 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-32, 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-32 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-32 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

Aurelia Bogedica

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 |
|---|---|---|---|
| 850 | 506013188TF323P | 05060131888507 | Rebreath With Valve |
| 851 | 506013188TF323P | 05060131888514 | Rebreath With Filter Paper |
| 852 | 506013188TF323P | 05060131888521 | Rebreath Pocket Face Mask |
| 853 | 506013188TF323P | 05060131888538 | Replacement Valve |
| 854 | 506013188TF323P | 05060131888545 | Printed Pouch With Rebreath |
| 855 | 506013188TF323P | 05060131888552 | Plain Pouch With Rebreath |
| 2851 | 506013188TF323P | 05060186996004 | Training Rebreath with Filter Paper on a Roll |
| 94260-5 | 506013188TF323P | 05060738579068 | Businesscare Resuscitation Device with Valve |
| C380 | 506013188TF323P | 05060738578856 | Lifemarque Resuscitation Face Shield |
| X1177 | 506013188TF323P | 05060738579174 | BCB Mouth to Mouth Pocket Face Mask (White) |
| X1330 | 506013188TF323P | 05060497998810 | Red Cross NZ Mouth to Mouth Resuscitation Device with Valve |
| X1542 | 506013188TF323P | 05060186995038 | Tranter Training Red Keyring Pouch with Filter Paper Rebreath |
| X2823 | 506013188TF323P | 05060738579136 | LE West Pocket Mask with 02 Inlet in Polybag (M6360) |
| X6681 | 506013188TF323P | 05060186996097 | St John Wales resus valve in keyring pouch (Yellow) |
| X7319 | 506013188TF323P | 05060738579006 | St Andrews mouth to mouth with filter paper |
| X7445 | 506013188TF323P | 05060738579013 | St Andrews resus mask with valve in blue keyring pouch |
| X7446 | 506013188TF323P | 05060186998206 | St Andrews Australia Red Keyring Pouch inc Resus Mask |
| X7471 | 506013188TF323P | 05060497998117 | St Andrews Rebreath with Filter Paper |
| X8004 | 506013188TF323P | 05060186997643 | MOHS Workplace Health keyring with rebreath (black) |
| X852 | 506013188TF323P | 05060186993157 | Rebreath Mouth to Mouth Pocket Face Mask in Poly Bag |
| X8700 | 506013188TF323P | 05060186993157 | Ouch Training Blue Keyring Pouch With Rebreath |
| X8790 | 506013188TF323P | 05060738579181 | Safe and Sound keyring pouch inc resus valve |
| X9808 | 506013188TF323P | 05060738579143 | Irish Red Cross Keyring Pouch (Red) Including Resus |
| X7851 | 506013188TF323P | 05060738579150 | Mini First Aid Kit Ltd Rebreath in Keyring Pouch - Printed |
| X1027 | 506013188TF323P | 05060497990142 | HCL Purple Keyring Pouch with Rebreath |

| | |
|---|---|
| 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** |


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**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

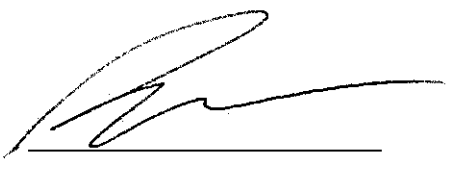
DA - Underskrevet:
Person, der er ansvarlig for overholdelse af reguleringen
På vegne af Reliance Medical Ltd

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 |