



EU Declaration of Conformity

to the 2017/745 Medical Device Regulation

2016/425 Personal Protective Equipment Regulation

We, Sri Trang Gloves (Thailand) Public Company Limited, declare under our sole responsibility that the medical device stated below meets all provisions of the Medical Device Regulation (EU) 2017/745 and Personal Protective Equipment Regulation (EU) 2016/425.

| | |
|--|--|
| Manufacturer: | Sri Trang Gloves (Thailand) Public Company Limited |
| Address: | 10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110 Thailand |
| Product Name: | Latex Examination Gloves, Powdered, Non-Sterile, EU Spec, Medical Grade |
| Product Group Code: | LX01 |
| Intended Purpose: | A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery |
| Device Classification: (As per MDR 2017/745) | Class I under Rule 1 and 5 according to Annex VIII |
| Basic UDI-DI: | 88591306LX01WN |
| CE marking first applied: | May 2020 |
| GMDN code and term: | 47173 Hevea-latex examination/treatment glove, powdered, non-antimicrobial |
| EMDN/CND: | T010201 (Examination/ Treatment Gloves, Latex) |
| Conformity Assessment Route: (As per MDR 2017/745) | Annexes II and III |



EC Representative for Sri Trang Gloves (Thailand) Public Company Limited is
Medical Device Safety Service GmbH.
Schiffgraben 41, 30175 Hannover, Germany

This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745 with:

- **Quality Management System certification to EN ISO 13485: 2016 under the supervision of TÜV SÜD PRODUCT SERVICE GMBH, certificate number Q5 099188 0004 Rev. 05.**
- **Availability of technical documentation per Annex II and Annex III of the Medical Device Regulation (EU) 2017/745**

This Declaration of Conformity is also issued on the basis of fulfilment the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III (Module D):

- **The conformity to type based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.**
- **The EU Type-Examination Certificate number 2777/10468-04/E00-00**

List of Applicable Regulations and Standards

| No. | Regulation/ Standard Number | Regulation/ Standard Name |
|-----|-----------------------------|--|
| 1 | MDR (EU) 2017/745 | Medical Device Regulation |
| 2 | PPE (EU) 2016/425 | Personal Protective Equipment Regulation |
| 3 | ISO 13485: 2016 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| 4 | ISO 9001: 2015 | Quality management systems – requirements |
| 5 | ISO 14971: 2019 | Medical devices – application of risk management to medical devices |
| 6 | EN 455-1: 2020 | Requirements and testing for freedom from holes |
| 7 | EN 455-2: 2015 | Requirements and testing for physical properties |
| 8 | EN 455-3: 2015 | Requirements and testing for biological evaluation |
| 9 | EN 455-4 : 2009 | Requirements and testing for shelf life determination |
| 10 | ISO 10993-1: 2018 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process |
| 11 | ISO 10993-5: 2009 | Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity |
| 12 | ISO 10993-10: 2010 | Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization |
| 13 | ASTM F1671: 2013 | Standard test method for resistance of materials used in protective clothing to |



| No. | Regulation/ Standard Number | Regulation/ Standard Name |
|-----|-----------------------------|---|
| | | penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system |
| 14 | ASTM D3578: 2019 | Standard specification for rubber examination gloves |
| 15 | EN 1041: 2008+A1: 2013 | Information supplied by the manufacturer of medical devices |
| 16 | EN ISO 15223-1: 2016 | EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied |
| 17 | ASTM D7160: 2016 | Determination of expiration dating for medical gloves |
| 18 | ASTM D7161: 2016 | Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions |
| 19 | EN 420: 2003+A1: 2009 | Protective gloves - General requirements and test methods |
| 20 | EN ISO 374-1: 2016+A1: 2018 | Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks |
| 21 | EN ISO 374-2: 2019 | Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration |
| 22 | EN ISO 374-4: 2019 | Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals |



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| No. | Regulation/ Standard Number | Regulation/ Standard Name |
|-----|-----------------------------|--|
| 23 | EN ISO 374-5: 2016 | Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks |
| 24 | EN 16523-1: 2015+A1: 2018 | Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact |

Established by,



Downloaded by , SUDARAT KETSIRIKUN on date 03 Aug 2021

Name: Ms. Sureerat Choosri

Position: Product Manager (Glove)

Date: 01 May 2021

DoC expires after 5 years

Place of issue of the EU Declaration of Conformity:

Sri Trang Gloves (Thailand) Public Company Limited

10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110 Thailand

Annex

(Product Description)

| Product Name (Device) | Product Code (KMAT)* | Product Specification Code** |
|---|---------------------------------|--------------------------------------|
| Latex Examination Gloves, Powdered, Non-Sterile, EU Spec, Medical Grade | DLXFSOG (With Color) DLXFBOG | LXXOGF-S-EU-M-NS LXXOGF-B-EU-M-NS |

Product Code (KMAT) means the specific code to identify the collective product design as a general code within the LX01 group. This Product Code (KMAT) is used to communicate in terms of contracts, general information, reports and sales.*

*Product Specification Code** means the glove specification code for individual products uses along with Product Code (KMAT). This Product Specification Code is also used to communicate in term of contracts, approbations and sales. With these detailed codes, it is possible to trace back individual designs and their specifications as agreed with the purchasing party.*