SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
Registration number 0107562000106
Headquarter: No. 110, Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand
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Fax: (66) 74-291-650
Office: No. 10 Soi 10, Phetkasem Road, Hat Yai, Hat Yai, Songkhla 90110 Thailand
Tel: (66) 74-344-663
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บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)
ทะเบียนเลขที่ 0107562000106
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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
Single Registration Number:	TH-MF-000010448
Product Name:	Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile
Product Group Code:	LO01
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:	88591306LO01V9
CE marking first applied:	May 2020
GMDN code and term:	47172 Hevea-latex examination/treatment glove, non-powdered, non-antimicrobial
EMDN/CND:	T010201 (Examination/ Treatment Gloves, Latex)
Conformity Assessment Route: (As per MDR 2017/745)	Annexes II and III

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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 2777/10467-05/E00-00

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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

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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	ISO 15223-1: 2021	ISO 15223-1 Symbols to be used with information to be suppliedby the manufacturer
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 ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
20	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
21	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
22	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

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No.	Regulation/ Standard Number	Regulation/ Standard Name
23	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
24	EN ISO 21420: 2020	Protective gloves – General requirements and test methods

Established by,

Nattawut.

_____

Name: Mr. Nattawut Promthong

Position: Technical Product Management Manager

Date: 28 April 2022

DoC expires after 5 years

Place of issue of the EU Declaration of Conformity:

Sri Trang Gloves (Thailand) Public Company Limited

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Annex

(Product Description)

Product Name (Device)	Product Code (KMAT)*	Product Specification Code**
Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile	DLOFSOG DLOFBOG DLOFWOG	LOOOGF-S-EU-M-NS LOOOGF-B-EU-M-NS LOOOGF-W-EU-M-NS

Product Code (KMAT) means the specific code to identify the collective product design as a general code within the LO01 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.*

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