

## **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.

<b>Manufacturer:</b>	Sri Trang Gloves (Thailand) Public Company Limited
<b>Address:</b>	10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110 Thailand
<b>Brand Name:</b>	Sensitive Protect <sup>®</sup>
<b>Item Number:</b>	202
<b>Product Name:</b>	Latex Examination Gloves, Powder Free, Offline Chlorination, Non-Sterile
<b>Product Spec Code :</b>	EU-LCMC-1T
<b>Intended Purpose:</b>	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
<b>Device Classification:</b> (As per MDR 2017/745)	Class I under Rule 1 and 5 according to Annex VIII
<b>Basic UDI-DI :</b>	88591306LC01TD
<b>CE marking first applied:</b>	May 2020
<b>GMDN code and term:</b>	47172, Powder Free Latex Examination Gloves
<b>EMDN/CND:</b>	T010201 (Examination/ Treatment Gloves, Latex)
<b>Conformity Assessment Route:</b> (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. 02.
- 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.

### 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: 2000	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



No.	Regulation/ Standard Number	Regulation/ Standard Name
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 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 374-2: 2014	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
22	EN 374-4: 2013	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
23	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

No.	Regulation/ Standard Number	Regulation/ Standard Name
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,


**Ms. Sureerat Choosri**

Product Manager (Glove)

Date: 18 June 2020

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