ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

CERTIFICATE

No. QS2 099188 0009 Rev. 05

Certificate Holder: **Sri Trang Gloves (Thailand) Public Company Limited**
10 Soi 10, Phetkasem Road
Hat Yai, Songkhla 90110
THAILAND

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves**

Standard: **ISO 13485:2016**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **5652586Rev1-721430166**

Effective Date: **2022-12-09**

Expiry Date: **2023-10-11**

Digitally signed by Bolea Petru
Date: 2023.08.03 18:50:36 EEST
Reason: MoldSign Signature
Location: Moldova

Date of Issue: 2022-12-12

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

SCC Accredited CB-MS OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS2 099188 0009 Rev. 05

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

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CERTIFICATE

No. QS2 099188 0009 Rev. 05

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
110/3 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
189, Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
85 Moo 6, Khuan Thani, Kantang, Trang 92110, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
110/19 Ban Khao Mai Deang, Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Date of Issue: 2022-12-12

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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TÜV SÜD America

C E R T I F I C A T E

No. QS2 099188 0009 Rev. 05

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
207/1 Padang Besa Road, Sadao, Sadao, Songkhla 90120, THAILAND

Facility Scopes: Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
88/8 Moo3, Samnak Kham, Sadao, Songkhla 90320, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Facility(ies): **Sri Trang Gloves (Thailand) Public Company Limited**
88/8, Moo 11, Khao Chai Rat, Pathio, Chumphon, 86210, THAILAND

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

Date of Issue: 2022-12-12

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

Certificate of Verification

Medical Device Safety Service GmbH (MDSS)

hereby declares that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

Sri Trang Gloves (Thailand) Public Company Limited
10 Soi 10, Phetkasem Road
90110 Hat Yai Songkhla
THAILAND

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2023-02-14
(YYYY-MM-DD)

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 650733

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
TF-MD-LF-01-101 rev. 10	Latex Examination Gloves, Powder Free, Polymer Coated, Non-Sterile LC01	47172	I	EU Declaration of Conformity (LC01) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180939
TF-MD-LF-01-103 rev. 01	Latex Examination Gloves, Powder Free, Polymer Coated, Non-Sterile LC02	47172	I	EU Declaration of Conformity (LC02) Signed 03 January 2023	N.A.	N.A.	DE/CA09/00180939
TF-MD-LF-01-102 rev. 09	Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile LO01	47172	I	EU Declaration of Conformity (LO01) Signed 01 September 2022	N.A.	N.A.	DE/CA09/00180939
TF-MD-LP-01-101 rev. 09	Latex Examination Gloves, Powdered, Non-Sterile LX01	47173	I	EU Declaration of Conformity (LX01) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180943
TF-MD-NF-01-101 rev. 09	Nitrile Examination Gloves, Powder Free, Polymer Coated, Non-Sterile NC01	56286	I	EU Declaration of Conformity (NC01) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
TF-MD-NF-01-102 rev. 09	Nitrile Examination Gloves, Powder Free, Polymer Coated, Accelerator Free, Non-Sterile NC02	56286	I	EU Declaration of Conformity (NC02) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945
TF-MD-NF-01-103 rev. 09	Nitrile Examination Gloves, Powder Free, Chlorinated, Non-Sterile NO01	56286	I	EU Declaration of Conformity (NO01) Signed 01 September 2022	N.A.	N.A.	DE/CA09/00180945
TF-MD-NF-01-104 rev. 09	Nitrile Examination Gloves, Powder Free, Chlorinated, Non-Sterile NO02	56286	I	EU Declaration of Conformity (NO02) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945
TF-MD-NF-01-105 rev. 09	Nitrile Examination Gloves, Powder Free, Chlorinated, Accelerator Free, Non-Sterile NO03	56286	I	EU Declaration of Conformity (NO03) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
TF-MD-NF-01-106 rev. 09	Nitrile Examination Gloves, Powder Free, Chlorinated, Non-Sterile NO04	56286	I	EU Declaration of Conformity (NO04) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945

*The registration number has been issued by the German Competent Authority.

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
Registration number 0107562000106
Headquarter: No. 110, Kanjanavanit Road, Pahtong,
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Fax: (66) 74-291-650
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Hat Yai, Songkhla 90110 Thailand
Tel: (66) 74-344-663
Fax: (66) 74-344-677, 74-237-423, 74-237-832

บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)
ทะเบียนเลขที่ 0107562000106
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เบอร์แฟกซ์: 074-291-650
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เบอร์แฟกซ์: 074-344-667, 074-237-423, 074-237-832

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

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
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บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)
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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

Single Registration Number: DE-AR-000005430

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 0012
- 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

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
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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

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:

No.	Regulation/ Standard Number	Regulation/ Standard Name
		Terminology and performance requirements for micro-organisms risks
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: 01 September 2022

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

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
Registration number 0107562000106
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บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)
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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 DLOFWLC	LOOOGF-S-EU-M-NS LOOOGF-B-EU-M-NS LOOOGF-W-EU-M-NS LOOLCF-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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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, Powdered, Non-Sterile
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

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
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เบอร์โทรศัพท์: 074-344-663
เบอร์แฟกซ์: 074-344-667, 074-237-423, 074-237-832

EC Representative for Sri Trang Gloves (Thailand) Public Company Limited is

Medical Device Safety Service GmbH.

Schiffgraben 41, 30175 Hannover, Germany

Single Registration Number: DE-AR-000005430

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 0012**
- **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 2777/10468-05/E00-00**

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
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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

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:

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No.	Regulation/ Standard Number	Regulation/ Standard Name
		Terminology and performance requirements for micro-organisms risks
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: 12 August 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, Powdered, Non-Sterile	DLXFSOG (With Color) DLXFBOG DLXSBOG	LXXOGF-S-EU-M-NS LXXOGF-B-EU-M-NS LXXOGS-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.*