

Declaration of Conformity

We

Manufacturer	Smart Glove International Pte. Ltd.
Address	3, Coleman Street #03-24, Singapore 179804 Singapore
Country	Singapore
Phone Number	+65 9639 8520
Single Registration Number	

declare with sole responsibility, that our product/s:

CND/ EMDN Code	CND/ EMDN Description	Product Name and Intended Purpose	Classification Rule & Risk Class per MDR (Annex VIII)
T01020203	POLYCHLOROPRENE EXAMINATION / TREATMENT GLOVES	Non-sterile Examination Gloves of Polychloroprene (Powder Free)	Rule 5, Risk Class I
T01020204	NITRILE EXAMINATION / TREATMENT GLOVES	Non-sterile Examination Gloves of Nitrile (Powder, Powder Free)	Rule 5, Risk Class I
T01020204	NITRILE EXAMINATION / TREATMENT GLOVES	Non-sterile, biodegradable Examination Gloves of Nitrile (Powder Free)	Rule 5, Risk Class I

meet the general safety and performance requirements of Regulation (EU) 2017/745 pertaining to medical devices. Pathway of conformity per Article 19 and Annex IV.

Intended Purpose Statement: Synthetic Latex Examination Gloves are intended for use in the medical field to protect patient and user from cross-contamination. The gloves are non-sterile, non-active, non-invasive and single-use. They are intended to be worn by healthcare personnel which conduct medical examination in dentistry, during diagnostic and therapeutic procedures and also for laboratory work. Lay persons can use the gloves when performing caregiving activities. The gloves can be used in clinical, home or industrial environment.

Basic UDI-DI:

- 955100527RE1003YF
- 955100527ME1004WG
- 955100527CE1005SG
- 95100527RE1007YP

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany, SRN: DE-AR-000006218 to act as European Authorized Representative as explicitly defined in Article 11 of Regulation (EU) 2017/745.

22 June 2022

Klang, Selangor

Date of Issue

Place of Issue

Johnson Chang



Printed Name

Signature

Chief Executive Officer

Smart Glove International Pte.Ltd

Title

Company

mdi Europa use only!

The necessary pre-requisites for placing the



mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day 22 of June 2022

mdi Europa GmbH
Langenhager Str. 71
30855 Langenhagen - GERMANY
Phone +49 511 39 08 95 30
Fax +49 511 39 08 95 39



mdi Europa

LED

CE Marking Experts for Medical Devices

Doc. No: TF-002	SMART GLOVE CORPORATION SDN. BHD.	
Eff Date: 10 Jun 2022	1.4 DoC	Revision No: 01.00

Declaration of Conformity

We

Manufacturer	Smart Glove Corporation Sdn. Bhd.
Address	Lot 6487, Batu 5 3/4 Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan, Malaysia
Country	Malaysia
Phone Number	+603291 6100
Single Registration Number	

declare with sole responsibility, that our product/s:

CND/ EMDN Code	CND/ EMDN Description	Product Name and Intended Purpose	Classification Rule & Risk Class per MDR (Annex VIII)
T01020203	POLYCHLOROPREN EXAMINATION / TREATMENT GLOVES	Non-sterile Examination Gloves of Polychloroprene (Powder Free)	Rule 5, Risk Class I
T01020204	NITRILE EXAMINATION / TREATMENT GLOVES	Non-sterile Examination Gloves of Nitrile (Powder, Powder Free)	Rule 5, Risk Class I
T01020204	NITRILE EXAMINATION / TREATMENT GLOVES	Non-sterile, biodegradable Examination Gloves of Nitrile (Powder Free)	Rule 5, Risk Class I

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Basic UDI-DI:

- 955101212RE1003TX
- 955101212ME1004RY
- 955101212CE1005MY
- 955101212RE1007U7

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany, SRN: DE-AR-000006218 to act as European Authorized Representative as explicitly defined in Article 11 of Regulation (EU) 2017/745.

Doc. No: TF-002	SMART GLOVE CORPORATION SDN. BHD.	
Eff Date: 10 Jun 2022	1.4 DoC	Revision No: 01.00

22 June 2022

Klang, Selangor

Date of Issue

Place of Issue

Johnson Chang



Printed Name

Signature

Chief Executive Officer

Smart Glove Corporation Sdn Bhd

Title

Company

mdi Europa use only!

The necessary pre-requisites for placing the CE mark on the above product and marketing them in all Member States of the European Union, have thus been fulfilled.



mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen GERMANY
Phone +49 511 39 08 95 30
Fax +49 511 39 08 95 39

Signed this day 23 of June 20 22

mdi Europa *EO*
CE-Marking Experts for Medical Devices