SMART GLOVE CORPORATION SDN. BHD.
Company No. 403570-D

GST ID : 000033816576

EU DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (MDR) (2017/745) and Personal Protective Equipment (PPE) Regulation (2016/425)

Manufacturer :
Name & Address:
Smart Glove Corporation Sdn Bhd
Lot 6487, Batu 5¾, Sementa, Jalan Kapar,
42100 Klang, Selangor Darul Ehsan, Malaysia

European Authorized Representative
Name & Address:
Mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
SRN: DE-AR-000006218

Product Name : Todent Heavy Nitrile 9Inch 6-7mil
Model : XS, S, M, L, XL
UDI-DI : 955101212E111888EE
Classification : Class I for Medical Device (Rule 5, Annex VIII MDR), Cat III for PPE

CONFORMITY ASSESSMENT PROCEDURE

Regulation (EU) 2017/745: Annex II + III
Harmonized standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009

Regulation (EU) 2016/425:
Harmonized standards: EN 420:2003+A1:2009, EN ISO 374-1:2016, EN ISO 374-5:2016
The notified body SATRA Technology Europe Ltd, number 2777 performed the EU type examination (Module B) and issued EU type-examination certificate number 2777/13372-01/E00-00. The PPE is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SATRA Technology Europe Ltd, number 2777.

We hereby declare that the above-mentioned product meets the provision of the Regulation (EU) 2017/745 and Regulation (EU) 2016/425. This declaration of conformity is issued under the sole responsibilities of Smart Glove Corporation Sdn Bhd.

Authorised Signatory

Name: Ms. Poppy Farah Rosa
Function: QA/RA Manager
Date: 14/04/2022
Place: Klang, Malaysia