

**EU DECLARATION OF CONFORMITY**  
**Regarding Medical Device Regulation (MDR) (2017/745) and Personal Protective**  
**Equipment (PPE) Regulation (2016/425)**

**Manufacturer**

*Name & Address:*

**GX Corporation Sdn Bhd (Specialty Plant)**  
Plot 6497-A, Lorong Haji Abdul Manan, 5<sup>3</sup>/<sub>4</sub>  
Milestone, 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** : Five fingered blue powder free nitrile examination gloves  
a) 3mil powder free nitrile examination gloves  
b) 4mil powder free nitrile examination gloves  
**Model** : XS, S, M, L, XL, XXL  
**UDI-DI** : 955101212E111888EE  
**Classification** : Class I for Medical Device (Rule 1, 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+A1:2018, EN 374-2:2014, EN ISO 374-5:2016, EN 16523, ISO 16604.

The notified body SATRA Technology Europe Ltd, number 2777 performed the EU type examination (Module B) and issued EU type-examination certificate number 2777/12322-02/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 GX Corporation Sdn Bhd (Specialty Plant). GX Corporation Sdn Bhd (Specialty Plant) is an affiliated company with Smart Glove Corporation Sdn Bhd and Smart Glove Corporation Sdn Bhd has appointed Mdi Europa GmbH as their European Representative.



Authorised Signatory

Name: Ms. Poppy Farah Rosa

Function: QA/RA Manager

Date: 21/02/2022

Place: Klang, Malaysia