

EU Declaration of Conformity

Manufacturer	GX Corporation Sdn Bhd (Specialty Plant)
Address	Plot 6497-A, Lorong Haji Abdul Manan, Batu 5 ¾ Sementa Jalan Kapar, 42100 Klang, Selangor, Malaysia
Authorized Representative Name SRN (Single Registration Number)	Emergo Europe B.V NL-AR-000000116
Authorized Representative Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
Notify Body Name	SATRA Technology Europe Ltd (Number: 2777)
Notify Body Address	Bracetown Business Park Clone, DY15 YN2P, Ireland
Name of the Device	Powder Free Nitrile Metal Detectable Glove
Trade Name	MetalMan (PPE Cert Number: 2777/14784-02/E0-00)
Glove Sizes Available	XS, S, M, L, XL and XXL
Classification	Category III for Annex II of the PPE Regulation (EU) 2016/425
Intended Use	Intended to wear on the hands for medical examination to provide a barrier against cross contamination and other contaminants.
Conformity assessment route	GX Corporation Sdn Bhd (Specialty Plant) uses the following procedures for the CE-labelling of our products: Category III: The PPE is subject to the conformity assessment procedure based on internal procedure control plus supervised product checks at random intervals (Module C2) under the surveillance of the notified body.

This declaration of conformity is issued under the sole responsibility of GX Corporation Sdn Bhd (Specialty Plant). We hereby declare that the device specified above meets the provision of the PPE Regulation (EU) 2016/425 for personal protective equipment and relevant harmonized standard as follows:



ISO 9001:2015	Quality Management Systems Requirements
EN 21420:2020	Protective gloves – General Requirements and Test Methods
EN 374-1	Protective Gloves against Dangerous Chemicals and Micro-organisms – Part 1: Terminology and Performance Requirements
EN 374-2	Protective Gloves against Dangerous Chemicals and Micro-organisms – Part 2: Determination of Resistance to Penetration
EN 374-4	Protective Gloves against Dangerous Chemicals and Micro-organisms – Part 4: Determination of Resistance to Degradation by Chemicals
EN 374-5	Protective Gloves against Dangerous Chemicals and Micro-organisms – Part 5: Terminology and Performance Requirements for Micro-organisms Risks
EN 16523-1	Determination of Material Resistance to Permeation by Chemicals – Part 1: Permeation by Liquid Chemical under Conditions of Continuous Contact

This declaration is supported by the Quality Management System certified to ISO 9001 issued by TÜV SÜD America Inc. All supporting documentation is retained at the premises of the manufacturer.


5th April 2023

Klang, Selangor

Date of Issue

Place of Issue

Mr. Hew Yew Fook



Printed Name

Signature

Chief Operating Officer

GX Corporation Sdn Bhd (Specialty Plant)

Title

Company

