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 Non-Sterile Examination Glove
Trade Name	Gen-X & iDental (i) 3-4mil - PPE Cert Number: 2777/12322-02/E00-00 (ii) 6 mil - PPE Cert Number: 2777/13372-01/E00-00 (ii) 13 mil - PPE Cert Number: 2777/11822-01/E00-00
Glove Sizes Available	XS, S, M, L, XL and XXL
Classification	Class I, Rule 5 for MDR Regulation (EU) 2017/745 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: Class I: EC conformity declaration according to Annex IV + Annex VIII of MDR Regulation (EU) 2017/745 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 MDR Regulation (EU) 2017/745 for medical devices, PPE Regulation (EU) 2016/425 for personal protective equipment and relevant harmonized standard as follows:

EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 13485:2016 MDSAP	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 9001:2015	Quality Management Systems Requirements
EN 455-1:2020	Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes
EN455-2:2015	Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties
EN 455-3:2015	Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation
EN 455-4:2009	Medical Gloves for Single Use – Part 4: Requirements and Testing for Shelf-Life Determination
ASTM D6319-19	Standard Specification for Nitrile Examination Gloves for Medical Application
EN 420:2003+A1:2009	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 13485 issued by TÜV SÜD Product Service GmbH. All supporting documentation is retained at the premises of the manufacturer.

5th April 2023 — Date of Issue

Klang, Selangor — Place of Issue

Mr. Hew Yew Fook — Printed Name

Signature

Chief Operating Officer — Title

GX Corporation Sdn Bhd (Specialty Plant) — Company