

EU Declaration of Conformity

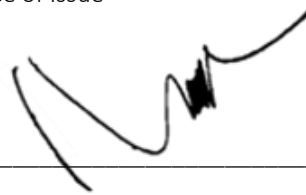
Manufacturer	GX Corporation Sdn Bhd (Specialty Plant)
Address	Plot 6497-A, Lorong Haji Abdul Manan, Batu 5 ¼ Sementa Jalan Kapar, 42100 Klang, Selangor, Malaysia
Authorized Representative Name SRN (Single Registration Number)	Emergo Europe B.V NL-AR-000000116
Authorized Representative Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
Name of the Device	Powder Free Nitrile Non-Sterile Examination Glove
Trade Name	ToDent® Protect Classic, ToDent® Touch Excellent
Intended Use	Intended to wear on the hands for medical examination to provide a barrier against cross contamination and other contaminants.
Classification	Class I, Rule 5 for MDR Regulation (EU) 2017/745
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

This declaration of conformity is issued under the sole responsibility of GX Corporation Sdn Bhd (Specialty Plant). We hereby declare that the medical device specified above meets the provision of the MDR Regulation (EU) 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by TUV SUD Product Service GmbH. All supporting documentation is retained at the premises of the manufacturer.

14 March 2024**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

