

EC DECLARATION OF CONFORMITY

GST ID: 002081161216

We, GX Corporation Sdn Bhd (Speciality Plant) herewith declare that the following mentioned products are manufactured in conformity with the provisions of Medical Device Directive (MDD) 93/42/EEC and Harmonized Standards as listed below.

All supporting documentation is retained under the premises of the manufacturer

Manufacturer and Its Address	Smart Glove Corporation Sdn Bhd Lot 6487, Batu 5 ¾, Sementa, Jalan Kapar 42100 Klang, Selangor Darul Ehsan, Malaysia
Authorized Representative	Mdi Europa GmbH Langenhagener Str. 71 30855 Langenhagen
Product Name	ToDent Premium 3mil Powder Free Nitrile Exam Finger Textured Blue Glove ToDent Excellent 3.5mil Powder Free Nitrile Exam Finger Textured Blue Glove ToDent Heavy 4.0mil Powder Free Nitrile Exam Finger Textured Blue Glove
Product Classification (according to MDD 93/42/EEC, Annex VII)	CLASS 1, NON-STERILE
Applicable Regulation	MEDICAL DEVICE DIRECTIVE 93/42/EEC
Harmonized Standard Compliance	EN 455 PART – 1,2, 3&4

Yours Faithfully:

Poppy Farah Rosa

QA/RA Manager

Date: 12th June 2020

