EU Declaration of Conformity

Manufacturer	Smart Glove Corporation Sdn Bhd
Address	Lot 6487, Batu 5 ¾ Sementa Jalan Kapar, 42100 Klang, Selangor, Malaysia
Authorized Representative Name SRN (Single Registration Number)	Mdi Europa GmbH DE-AR-000006218
Authorized Representative Address	Langenhagener Str. 71, 30855 Langenhagen, Germany
Name of the Device	Non Sterile Polychloroprene Examination Glove Powder Free Non Sterile Nitrile Examination Glove (Powdered, Powder Free) Non Sterile Biodegradable Nitrile Examination Glove Powder Free
Trade Name	Gen-X, iDental
Glove Sizes Available	XS, S, M, L, XL and XXL
Classification	Class I, Rule 5 for MDR Regulation (EU) 2017/745
Basic UDI-DI	955101212RE1003TX 955101212ME1004RY 955101212CE1005MY 955101212RE1007U7
Intended Use	Intended to wear on the hands for medical examination to provide a barrier against cross contamination and other contaminants.
Conformity assessment route	Smart Glove Corporation Sdn Bhd 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 Smart Glove Corporation Sdn Bhd. We hereby declare that the device specified above meets the provision of the MDR Regulation (EU) 2017/745 for medical devices 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	Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes
EN455-2	Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties
EN 455-3	Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation
EN 455-4	Medical Gloves for Single Use – Part 4: Requirements and Testing for Shelf-Life Determination
ASTM D6977	Standard Specification for Polychloroprene Examination Gloves for Medical Application
ASTM D6319	Standard Specification for Nitrile Examination Gloves for Medical Application

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	Klang, Selangor
Date of Issue	Place of Issue
Mr. Hew Yew Fook	
Printed Name	Signature
Chief Operating Officer	Smart Glove Corporation Sdn Bhd
Title	Company