

Declaration of Conformity Certificate

We

Manufacturer : Viet Glove Corporation
Address: Plot 03, Map No 37, Cau Sat Hamlet, Lai Hung Village, Bau Bang District, Binh Duong Province
Country : Viet Nam
Phone Number : +84 (650) 3535 778/779

Declare with sole responsibility, that our product/s:

UMDNS Code	UMDNS Description	Internal Product Name	Classification Rationale Per MDD
11882	Examination/Treatment	Powder Free Nitrile Examination Gloves	Class I

Meet, the essential requirements of Council Directive 93/42/EEC as amended by 2007/47/EEC pertaining to medical devices. Pathway of conformity per Annex II.

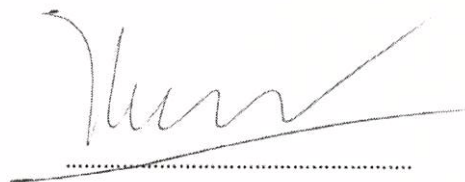
Notified Body : (British Standard Institute – 0086)


The product(s) identified above meet requirements of the Medical Devices Directive by meeting the following standards

Standard No	Standard Description
EN455-1	Medical Gloves for Single Use. Requirements & Testing for Freedom of Holes
EN455-2	Medical Gloves for Single Use. Requirements & Testing for physical properties
EN455-3	Medical Gloves for Single Use. Requirements & Testing for Biological Evaluation

We hereby appoint mdi Europa GmbH, Langaenhagener Str.71, 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2 (g) of Directive 98/79/EEC

Signed this day, 25th of January 2019




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 THE MEDICAL DEVICE SERVICE-MANAGEMENT