

Certificate of CE-Registration



mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG) für den Hersteller

Viet Glove Corporation
Plot 03, Map No. 37
Cau Sat Hamlet, Lai Hung Village
Bau Bang District, Binh Duong Province
Vietnam

as stipulated and demanded by the afore-mentioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

Medical Device	UMDNS Code	Registration-No.
Powder Free Nitrile Examination Glove	11882 –Class I	DE/CA09/0760/1900

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG.

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

February 2016

Werner Sander
President & CEO

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.

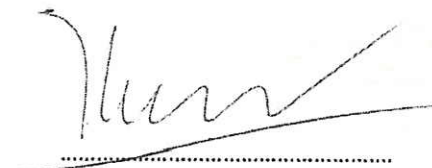
Notified Body : (British Standard Insitute – 0086)

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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 05-10-2019
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 THE MEDICAL DEVICE SERVICE MANAGEMENT