

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

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BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 50 Factories (Malaysia, Thailand, Vietnam & China), 800 Production Lines, 100 Billion Gloves Per Annum, 22,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

DECLARATION OF CONFORMITY

Manufacturing Site : TG Medical Sdn. Bhd.
: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru,
41050, Klang, Selangor D.E., Malaysia

European Authorized Representative : Top Glove Europe GmbH
Bliersheimer Str. 80, D-47229 Duisburg,
Germany.

Name of Device : Sterile Latex Surgical Powder Free Gloves
Size : 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Classification : Class IIa
Conformity Assessment Procedure : Annex V
Brand Name : HYDROFEEL

We herewith declare with our own responsibility that above mentioned product(s) with CE mark meet the provisions of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of manufacturer.

Applicable Standards and Reference;

No	Standard	Descriptions	Date Published
1.	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	March 2016
2.	EN 455-1:2020+1:2022	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	February 2022
3.	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
4.	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
5.	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.	October 2009
6.	EN ISO14971:2019+A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	December 2021

**"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.
BE HONEST AND NO CHEATING"**

DP 25/03/21/TGT

Rev.: 0 (RA / F21)

7.	ISO 2859-1:2011	Sampling procedures and table for inspection by attributes	June 2011
8.	EN ISO 11737-1:2018/ A1:2021	Sterilization of health care products Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)	June 2021
9.	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	May 2020
10.	EN ISO 11137-1:2015/ A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/Amd 2:2018)	November 2019
11.	EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	June 2015
12.	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)	December 2020
13.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	June 2009
14.	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	August 2013
15.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
16.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
17.	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	January 2020
18.	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	January 2020
19.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	September 2021
20.	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
21.	MEDDEV 2.4/1	2.4/1 Classification of Medical Device	Revision 9, June 2010
22.	MEDDEV 2.5/9	2.5/9 Implication of the Medical Device Directive 93/42/EEC in Relation to Medical Device Containing Natural Rubber Latex	Revision 1, February 2004

23.	MEDDEV 2.5/10	2.5/10 Guideline for Authorized Representative	January 2012
24.	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
25.	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013

EC Certificate(s) : MY19/1811030189
Notified Body : SGS Belgium NV,
SGS House Noorderlaan,
872030 Antwerp Belgium.

CE Number : 1639



Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
Date: 7th December 2023

