DECLARATION OF CONFORMITY
MEDICAL DEVICE REGULATION 2017/745
PERSONAL PROTECTIVE EQUIPMENT REGULATION EU 2016/425

We,

F. Bosch International Limited
10/F Lee King Industrial Building,12 Ng Fong Street
San Po Kong, Kowloon, Hong Kong

hereby declare under our sole responsibility that,
the below non-sterile examination / protective glove for single use
Classification: Class I, according to Rule 5 in annex VIII of MDR 2017/745; Category III, according to PPE Regulation (EU) 2016/425
Conformity Assessment Route: Annexes II and III

Family Name: F. Bosch Latex Powdered / Powder-Free Examination Gloves
Basic UDI-DI: ++B879FBGLV-1W4
SRN: (To be determined after registration to the country)

Color/Style		**XSmall**	**Small**	**Medium**	**Large**	**XLarge**
White Powdered	**Model Number**	FBGLVE-1021	FBGLVE-1022	FBGLVE-1023	FBGLVE-1024	FBGLVE-1025
	Product Name	Latex White Gloves	Latex White Gloves	Latex White Gloves	Latex White Gloves	Latex White Gloves
White Powder-Free	**Model Number**	FBGLVE-1031	FBGLVE-1032	FBGLVE-1033	FBGLVE-1034	FBGLVE-1035
	Product Name	Latex White Gloves	Latex White Gloves	Latex White Gloves	Latex White Gloves	Latex White Gloves
Blue Powdered	**Model Number**	FBGLVE-1041	FBGLVE-1042	FBGLVE-1043	FBGLVE-1044	FBGLVE-1045
	Product Name	Latex Blue Gloves	Latex Blue Gloves	Latex Blue Gloves	Latex Blue Gloves	Latex Blue Gloves
Black Powder-Free	**Model Number**	FBGLVE-1051	FBGLVE-1052	FBGLVE-1053	FBGLVE-1054	FBGLVE-1055
	Product Name	Latex Black Gloves	Latex Black Gloves	Latex Black Gloves	Latex Black Gloves	Latex Black Gloves

Product Intended use: The powdered/powder-free latex examination glove is a single use medical device, which intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner, which usually used for conducting medical examination, dentistry, clinical examination, diagnostic and therapeutic procedures and also for laboratory purposes, except surgery.

meets all the provisions of the MDR 2017/745 any other relevant EU legislation which apply to them.

The CE marked product described above also confirms with the applicable provisions of Regulation (EU) 2016/425 on Personal Protective Equipment for Category III. Below notified body performed the EU type-examination (Module B) and issued the EU type-examination certificates (reference to that certificate). The conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or based on quality

assurance of the production process under surveillance of the notified body (Module D) under surveillance of the notify body:

SATRA Technology Europe Ltd, ID No. 2777
Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland

List of applicable standards

No.	Regulation / Standard Number	Regulation / Standard Name
1	EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN 455-1:2000	Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
4	EN 455-2:2015	Medical gloves for single use – Part 2: Requirements and testing for physical properties
5	EN 455-3:2015	Medical gloves for single use – Part 3: Requirements and testing for biological evaluation
6	EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
7	EN 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing
8	EN 1041:2008+A1:2013	Medical devices – Information supplied by the manufacturer
9	EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
10	EN 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks
11	EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks
12	EN 420:2003+A1:2009	Protective gloves – General requirements and test methods

Sign for and on behalf of F. Bosch International Ltd,

Li, Mei Yan Christina
Manager
Date: 28 Sep 2021; Location: Hong Kong

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