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; Class III, according to PPE Regulation (EU) 2016/425
Conformity Assessment Route: Annexes II and III

F. Bosch Vinyl Powdered/Powder-Free Examination Gloves
Basic UDI-DI: ++B879FBGLVE-22M
SRN: (To be determined after registration to the country)

Color/Style		**XSmall**	**Small**	**Medium**	**Large**	**XLarge**
Powdered Clear	**Model Number**	FBGLVE-2011	FBGLVE-2012	FBGLVE-2013	FBGLVE-2014	FBGLVE-2015
	Product Name	Vinyl Clear Gloves	Vinyl Clear Gloves	Vinyl Clear Gloves	Vinyl Clear Gloves	Vinyl Clear Gloves
Powder-Free Clear	**Model Number**	FBGLVE-2021	FBGLVE-2022	FBGLVE-2023	FBGLVE-2024	FBGLVE-2025
	Product Name	Vinyl Clear Gloves	Vinyl Clear Gloves	Vinyl Clear Gloves	Vinyl Clear Gloves	Vinyl Clear Gloves
Powdered Blue	**Model Number**	FBGLVE-2031	FBGLVE-2032	FBGLVE-2033	FBGLVE-2034	FBGLVE-2035
	Product Name	Vinyl Blue Gloves	Vinyl Blue Gloves	Vinyl Blue Gloves	Vinyl Blue Gloves	Vinyl Blue Gloves
Powder-Free Blue	**Model Number**	FBGLVE-2041	FBGLVE-2042	FBGLVE-2043	FBGLVE-2044	FBGLVE-2045
	Product Name	Vinyl Blue Gloves	Vinyl Blue Gloves	Vinyl Blue Gloves	Vinyl Blue Gloves	Vinyl Blue Gloves

Product Intended use: The vinyl powdered/powder-free 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) 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 ISO 21420:2020	Protective gloves – General requirements and test methods

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

Li, Mei Yan Christina
Manager
Date: 1 Sep 2021; Location: Hong Kong

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