

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 for MDR: Annexes II and III

Family name: F. Bosch Nitrile Powder-Free Examination Gloves

Basic UDI-DI: ++B879FBGLVE-32P

SRN: (To be determined after registration to the country)

Color/Style		XSmall	Small	Medium	Large	XLarge
Black Extra Strong	Model Number	FBGLVE-3011	FBGLVE-3012	FBGLVE-3013	FBGLVE-3014	FBGLVE-3015
	Product Name	Nitrile Black Gloves	Nitrile Black Gloves	Nitrile Black Gloves	Nitrile Black Gloves	Nitrile Black Gloves
Black Thin Style	Model Number	FBGLVE-3021	FBGLVE-3022	FBGLVE-3023	FBGLVE-3024	FBGLVE-3025
	Product Name	Nitrile Black Gloves	Nitrile Black Gloves	Nitrile Black Gloves	Nitrile Black Gloves	Nitrile Black Gloves
Violet Blue	Model Number	FBGLVE-3031	FBGLVE-3032	FBGLVE-3033	FBGLVE-3034	FBGLVE-3035
	Product Name	Nitrile Violet Blue Gloves	Nitrile Violet Blue Gloves	Nitrile Violet Blue Gloves	Nitrile Violet Blue Gloves	Nitrile Violet Blue Gloves
Blue Extra Strong	Model Number	FBGLVE-3041	FBGLVE-3042	FBGLVE-3043	FBGLVE-3044	FBGLVE-3045
	Product Name	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves
Blue	Model Number	FBGLVE-3051	FBGLVE-3052	FBGLVE-3053	FBGLVE-3054	FBGLVE-3055
	Product Name	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves
Blue Xtend	Model Number	FBGLVE-3061	FBGLVE-3062	FBGLVE-3063	FBGLVE-3064	FBGLVE-3065
	Product Name	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves	Nitrile Blue Gloves

Product Intended use: The powder-free nitrile 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 conforms with the applicable provisions of Regulation (EU) 2016/425 on Personal Protective Equipment for Category III (Module C2 or D). The conformity to type based on quality assurance of the production process under surveillance of the notified 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 15223-1:2021	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: 25 Jul 2022; Location: Hong Kong



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