# 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 | **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 |

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 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

F. Bosch International Limited
10/F, Lee King Industrial Building, 12 Ng Fong Street, San Po Kong,
Kowloon, Hong Kong
Web: www.fbosch.com.hk Email: info@fbosch.com.hk

EC REP MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany