

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 Disposable Shoes Cover

Classification: Class I, according to Rule 1 in annex VIII of MDR 2017/745; Category I, according to PPE Regulation (EU) 2016/425

Conformity Assessment Route: Annexes II and III

Family Name: F. Bosch Shoes Cover

Basic UDI-DI: ++B879PRCL166G

SRN: HK-MF-000029001

Product Code	Product Description
PRCL-1009	F. Bosch Shoe Cover CPE Blue
PRCL-1010	F. Bosch Shoe Cover CPE White
PRCL-1076	F. Bosch Shoe Cover (PP+CPE) Anti Slippery
PRCL-1077	F. Bosch Overboot (PE) Embossed Blue
PRCL-1100	F. Bosch Overboot (PE) Embossed Clear

Product Intended use: Disposable shoe cover is intended to resistance to liquids, dust, and dirt. It helps user to prevent bacteria or germs from contaminating sterile areas and prevent cross-contamination in their place of work, like hospitals. It is usually used in hospital, laboratory, and places need high level of hygiene.

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 I.

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 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing
4	EN 1041:2008+A1:2013	Medical devices – Information supplied by the manufacturer
5	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

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



Li, Mei Yan Christina
Manager

Date: 30 Sep 2022; 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



MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany