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 cap
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 Disposable Cap
Basic UDI-DI: ++B879PRCL1166
SRN: HK-MF-000029001

Product Code	Product Description
PRCL-1004	F. Bosch Bouffant Cap with Elastic Cord White
PRCL-1005	F. Bosch Bouffant Cap with Elastic Cord Blue
PRCL-1006	F. Bosch Cap with Visor (without Snood) White
PRCL-1017	F. Bosch Mushroom Cap White
PRCL-1018	F. Bosch Mushroom Cap Blue
PRCL-1027	F. Bosch Cap with Visor (with Snood) White
PRCL-1028	F. Bosch Bouffant Cap White 60cm
PRCL-1033	F. Bosch Beard Mask White
PRCL-1054	F. Bosch Beard Mask Blue
PRCL-1058	F. Bosch Astronaut Cap with Facemask White
PRCL-1059	F. Bosch Astronaut Cap with Facemask Violet Blue
PRCL-1061	F. Bosch Shower Cap (PE)
PRCL-1067	F. Bosch Astronaut Cap Blue
PRCL-1068	F. Bosch Mushroom Cap Green
PRCL-1069	F. Bosch Mushroom Cap Orange
PRCL-1070	F. Bosch Mushroom Cap with Detectable Stripe Blue
PRCL-1081	F. Bosch Bouffant Cap Heavy White
PRCL-1082	F. Bosch Bouffant Cap Heavy Blue
PRCL-1091	F. Bosch Astronaut Cap with Facemask Blue
PRCL-1106	F. Bosch Mushroom Cap Red

Product Intended use: Disposable cap is intended to prevent hair, sweat and dust particles from escaping from the head area to cause any cross-contamination to the patients. Ideal for use in hospital, medical facilities, laboratory, food hygiene, food processing and service.

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

EC REP MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany