

Date 2022-05-03

EU Declaration of Conformity for Personal Protective Equipment Category III

We herewith declare that the following personal protective equipment

Cosmoplast Protection & Care Wax Earplugs

which is first placed on the market by CMC Consumer Medical Care GmbH, meets the applicable provisions, especially the essential health and safety requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

The object of the declaration is in conformity with the relevant Union harmonization legislation: EN 352-2:2002.

The notified body SGS Fimko Ltd, Takomotie 8, FI-00380 Helsinki, Finland (Notified Body No. 0598) performed the EU type examination (Module B) and issued the EU-type examination certificate No. 0598/PPE/22/2569.

The PPE is subject to the conformity assessment procedure based on product monitoring (Module C2) under surveillance of the notified body SGS Fimko Ltd, Takomotie 8, FI-00380 Helsinki, Finland (NB No. 0598).

The production site has certified its Quality Management System in accordance with ISO 9001: 2015 (Certificate Reg. No. 17800-A) and ISO 13485:2016 (Certificate Reg. No. 17800-M).

The EU Declaration of Conformity is issued under the sole responsibility of the CMC Consumer Medical Care GmbH.

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Responsible Person Regulatory Affairs

This document is valid until: 2024-03-12

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