

EC DECLARATION OF CONFORMITY

Manufacturer:

ELDO CARE CORPORATION LIMITED

Rm.1902, Easey comm. Bldg., 253-261 Hennessy Road, Wanchai, Hongkong

European Authorized Representative

Company: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, herewith declare that the product:

Product Name & Model:

ELFM3600: Non-woven Face Mask, Single-use, Ear-loop, 3-ply, non-sterile

Meet the provisions of the Council Directive 93/42/EEC which apply to them.

Harmonized standards or normative documents: EN 14683:2019+AC:2019 TYPE II BFE ≥98%

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark:



CONFORMITY ASSESSMENT ROUTE: ANNEX IX Rule 1

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of:

ELDO CARE CORPORATION LIMITED

Place, date Anhui, China May. 26th, 2020 Legally binding signature, Function Co-founder & CEO Ellen Wang

EC Declaration of Conformity

ELDO CARÉ CO., LIMITED

Authorized Signature(s)

For and on behalf of