



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.

Declares that the MDD described hereafter

Product name and model:

ELFM3600 - Non-Woven Face Mask, Ear-loop, 3-ply, non-sterile

Meet the provisions of the Council Directive 93/42/EEC & 2007/47/CE which apply to them.

Harmonized standards or normative documents :
EN 14683:2019+AC:2019 TYPE IIR BFE \geq 98%

The medical device has been assigned to class I according to Annex VII of the Directive 2007/47/CE. It bears the mark:



CONFORMITY ASSESSMENT ROUTE: Annex VII

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
Shanghai, China
Sep. 9th, 2020

Legally binding signature, Function
Co-founder & CEO
Ellen Wang

EC Declaration of Conformity

For and on behalf of
ELDO CARE CO., LIMITED

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Authorized Signature(s)

ELDO CODE	GIMA CODE	PRODUCT DESCRIPTION	PACKING
ELFM3600	20670	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile – singly packed	box 50pcs
ELFM3600	20700	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20695	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20697	GISAFE – color: pink Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20694	GISAFE – color: pink Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20698	GISAFE – color: white Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20699	GISAFE – color: light green Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20685	GISAFE – fantasy: cartoon Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20686	GISAFE – fantasy: peace Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20687	GISAFE – fantasy: stars Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20680	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20682	GISAFE – fantasy: cartoon Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20696	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 2000pcs (200 flowpack of 10 pcs)
ELFM3600	20701	GISAFE – color: black Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20688	GISAFE – fantasy: colours Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20689	GISAFE – fantasy: macarones Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20690	GISAFE – fantasy: skulls Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20691	GISAFE – fantasy: military Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs