



EU DECLARATION OF CONFORMITY

Manufacturer:

ELDO CARE CORPORATION LIMITED

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

European Authorized Representative

Lotus NL B.V.

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

SRN number: NL-AR-000000121

Declares that the MD described hereafter

Productnameandmodel:

ELFM3600 - Medical Face Mask, Ear-loop, 3-ply, non-sterile-Class 1

Basic UDI-DI: 489712189ELFM3600Z2

SRN: HK-MF-000008425

Meet the provisions of the (EU) 2017/745 Medical Device Regulation which apply to them.

Standards or normative documents:
EN 14683 :2019+AC :2019 TYPE IIR BFE≥98%

The medicaldevice has beenassigned to class I according to Rule 1, AnnexVIII of theRegulation (EU) 2017/745.

It bears the mark:



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

Sep. 14th,2021

EC Declaration of Conformity

Legallybindingsignature,Function

Co-founder &CEO

Ellen Wang

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

Intended Use: The intended use of a medical face mask is to help prevent large particles expelled by the wearer (e.g. spit, mucous) from reaching the patient or work environment. Fluids contacting the outer surface of the surgical mask will not immediately soak through to the interior of the surgical mask and contact the wearer’s lips or skin.