

EU DECLARATION OF CONFORMITY

(According to Regulation (EU) 2017/745)

Manufacturer:

ELDO CARE CORPORATION LIMITED

8/F Office 5 Mega Cube, 8 Wang Kwong Road,
Kowloon Bay, Hongkong
Manufacturer SRN: HK-MF-000008425

European Authorized Representative

Company: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands
AR SRN: NL-AR-000000121

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product Identification

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

Basic UDI-DI: 489712189ELFM3600Z2

Risk Classification

The above-mentioned medical device is classified as Class I (non-sterile, no measuring function) in accordance with Rule 1, Annex VIII of Regulation (EU) 2017/745.

Conformity Assessment Route

The conformity assessment has been carried out according to Regulation (EU) 2017/745:

- Annex II (Technical Documentation) and
- Annex III (Post-Market Surveillance)

Applied Harmonised Standards and Common Specifications

The conformity of the product with the applicable requirements of Regulation (EU) 2017/745 is demonstrated by compliance with the following harmonised standard:

- EN 14683:2025 – Type IIR Bacterial Filtration Efficiency (BFE) \geq 98%

(Bacterial Filtration Efficiency, Breathability, Resistance to liquid splashes, Microbial cleanliness)

CE Marking

The medical device bears the CE marking in accordance with Regulation (EU) 2017/745.



Additional Statement

This Declaration of Conformity is valid in conjunction with the release documentation for the respective batch of produced devices and remains valid provided that the product design, materials, and manufacturing processes remain unchanged.

Place , date

Anhui, China

Oct. 13th 2025

Legally binding signature, Function

Co-founder & CEO

Ellen Wang

EU Declaration of Conformity

For and on behalf of
ELDO CARE CO., LIMITED
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.