

# evercare<sup>®</sup> Medical face mask Multifix Guardline, standard, with earloops, type II

evercare<sup>®</sup> Medical face mask Multifix Guardline, standard with earloops, type II provides a barrier to minimize the direct transmission of infective agents between medical staff and patient. It is an allround face mask with high filtration capacity and low breathing resistance. Recommended to be used during dry surgery, with no risk of splashes.

## Key Features

- EN 14683:2019
- ▶ Bacterial Filtration Efficiency (BFE) ≥ 98%
- Single use
- Flexible nose wire for proper fit
- Color: Outer facing green, inner facing white



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REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
2858	Medical face mask Multifix Guardline Standard with earloops, type II, non-sterile, Green	175 x 90 mm	50 / 300

Sales Unit: Transport Carton

# Technical Summary

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### Regulations

The product complies with legal requirements for medical devices.

CE MD Wot made with natural rubber latex	
REACH regulation:	The products covered by this data sheet do not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).
Biological evaluation:	EN ISO 10993-05 EN ISO 10993-10
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, MDR class I
Compliance with product standards:	EN 14683:2019, Type II, Bacterial Filtration Efficiency (BFE) ≥98%
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN 1041

#### Material

Product Part	Raw Material & Characteristics	
Outer facing	Spunbond PP, green	
Filter media	Meltblown PP, white	
Inner facing	Spunbond PP, white	
Bindings	Spunbond PP, white	
Elastic earloops	Latex-free, white	
Nose wire	PE coated galvanize wire, 125 mm	

#### Warnings & Recommendations

Warnings	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.	
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.	
Disposal Recommendation	Dispose in accordance with local regulations.	
Shelf Life	3 Years	

#### **Packing information**

Package	Material	Size(L x W x H)mm	
Single Pack	N/A	N/A	
Dispenser Pack	Coated paper	185 x 100 x 80	
Transport Carton	Carton, TCF or ECF quality	213 x 197 x 260	
Packing Tape	PVC-free, Transparent	N/A	

#### Barcodes

REF	Single Pack	Dispenser	Transport Carton
2858	N/A	6438129312959	6438129512953

Evercare Medical AB is a partner that enables better lives for patients, facilitates everyday life for healthcare employees and contributes to lower care costs. We strive to reduce the environmental impact and, together with our suppliers, to improve working conditions throughout the value chain.