

Surgical masks and caps
Surgical masks



Multiguard

REF 2850

Type II
Tie-band, blue
Pack count: 50/300



Multifix Starline

REF 2855

Type II
Ear-loop, blue
Pack count: 50/300



Multiguard

REF 2851

Type II
Tie-band, green
Pack count: 50/300



Multifix

REF 2856

Type II
Ear-loop, green
Pack count: 50/300

Pirkimo dalis Nr. 94



Multiguard Antifog

REF 2865

Type II
Tie-band, antifog, green
Pack count: 50/300



Multifix Guardline

REF 2858

Type II
Ear-loop, green
Pack count: 50/300



Multifix Splash

REF 2875

Type IIR
Ear-loop, splash resistant,
green
Pack count: 50/300

Product Data Sheet

Surgical masks



Surgical mask Multiguard antifog REF 2865

Page 1 (3)

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Printed: 14.1.2013

REF	Colour/size	Fixation	
2865	Green, width 17,5 cm	Tie-band	
Classified as type II in the EN14683:2005 European standard Surgical masks – requirements and test methods, Annex A (informative). Bacterial Filtration Efficiency (BFE) > 99 % [NATURAL LATEX FREE]			
Raw materials: Outer coverstock Filter Inner coverstock Nose wire Ties Front antifog Back antifog			spunbond polypropylene, blue meltblown polypropylene, white hydrophilic polypropylene, white pe-coated galvanized wire spunbond polypropylene, white laminate white spunbonded polypropylene/transparent polyethylene laminate light blue PPU foam/spunbonded polypropylene
REACH regulations:			The product covered by this data sheet does not contain carcinogenic, mutagenic or toxic substances, 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).
Features:			An allround antifog surgical mask with high filtration capacity and low breathing resistance. Recommended to be used during dry surgery, with no risk of splashes.
Pack count:			50 pcs/dispenser, 6 dispensers of 50 pcs (= 300 pcs)/carton
Dispenser:			Cardboard 185 x 110 x 130 mm
Transport carton:			Cardboard 280 x 197 x 345 mm
Sales unit:			Transport carton (6 dispensers of 50 pcs)
Compliance with legal requirements:			Medical Devices Directive 93/42/EEC, Class I
Compliance with product standards:			EN 14683:2005, Type II
Quality standards:			The product is manufactured in compliance with ISO13485
Label information:			in accordance with EN ISO 15223-1 and EN1041
Storage recommendation:			Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sun light and other intensive light sources.
Disposal recommendation			Follow local instructions
Risk if reused:			The product is single use. If reused performance of product may deteriorate, cross contamination may occur

Produkto duomenų lapas

Chirurginės kaukės

ŠIAME PRODUKTO DUOMENŲ LAPE PATEIKIAMA KONFIDENCIALI INFORMACIJA

Chirurginė kaukė Multiguard antifog

REF 2865

Puslapis 1 (2)

Versija: 2013.03.04, rev. 4

Atspausdinta: 2013.03.04

REF	Spalva/dydis	Fiksacija	
2865	Žalia, plotis 17,5 cm	Raišteliai	
<p>Klasifikacijos tipas II pagal EN14683:2005 Europos standartas chirurginės kaukės.</p> <p>Bakterinis filtracijos efektyvumas (BFE) > 99%</p> <p>[be latekso] Be formaldehido Be nikelio</p>			
<p>Žaliavos: Išorinis sluoksnis Filtras Vidinis sluoksnis Nosies viela Ausų kilpos Išorinė anti-fog juostelė Vidinė anti-fog juostelė</p>			<p>Neaustas polipropilenas, mėlynas Ilydytas polipropilenas, baltas Hydrofolinis polipropilenas, baltas Dengta cinkuota viela Neaustas polipropilenas, baltas Laminatas baltas - Neaustas polipropilenas/skaidrus polietilenas Laminatas šviesiai mėlyna PPU puta/šviesintas polipropilenas</p>
REACH reglamentavimas:			Produktas, paminėtas šiame produkto duomenų lape, neturi savo sudėtyje medžiagų iš SVHC sąrašo, esančio paskutinėje išleistoje versijoje kandidatų sąrašė publikuotame Europos chemijos agentūros (ECHA).
Sudėtis:			Ultragarsiniu metodu užlydytos siūlės, atspari skysčiams, aukšto filtracijos efektyvumo, turinti anti-fog juostelę chirurginė kaukė. Rekomenduojama naudoti „sausų“ operacijų metu, su maža skysčių patekimo rizika. Filtracijos efektyvumas – min. 3 valandos
Pakuotė:			50 vnt/dėž., 6 dėž. Po 50 vnt (=300 vnt)/ kartoninė dėžė
Dėžutė:			Kartoninė dėžutė 185x110x130 mm
Transportinė dėžė:			Kartoninė dėžutė 280x197x345 mm
Pardavimo vienetas:			Transportinė dėžė (6 dėžutės po 50 vnt)
Laikymasis teisinės reglamentacijos:			Medicinos priemonių direktyvos 93/42/EEB, Klasė I
Laikymasis produkto standartų:			EN14683:2005, Tipas II
Kokybės standartai:			Produktas gaminamas laikantis ISO 13485
Etiketės informacija:			Atitinka EN ISO15223-1 ir EN1041
Laikymo sąlygos:			Rekomenduojama laikyti švarioje, sausoje vietoje aplinkos temperatūroje. Produktas turėtų būti apsaugotas nuo tiesioginių saulės spindulių ir kitų intensyvios šviesos spindulių.
Šalinimo rekomendacijos			Produkto ir pakuotės žaliavos perdirbimas arba mišrios atliekos

Description of the product: **Surgical mask Multiguard Antifog, special, green**

REF: **2865**

Brand: **evercare** Directive / Class: **MDD / I**

Intended use: Face masks are intended to be placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms during surgery or patient examination.

Compliance with Standards & Regulations

Product is in full compliance with following standards	EN 14683:2005, Type II
REACH regulation	The product covered by this product specification does not contain carcinogenic, mutagenic or toxic substances, 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).

Raw materials / Composition

Product part	Raw material	Raw material characteristics
Outer facing	See attached Thai Hospital product specification	
Filter	See attached Thai Hospital product specification	
Inner facing	See attached Thai Hospital product specification	
Bindings / ties	See attached Thai Hospital product specification	
Nose wire	See attached Thai Hospital product specification	
Front anti-fog	See attached Thai Hospital product specification	
Back anti-fog	See attached Thai Hospital product specification	
Dispenser box	Duplex paper, weight 350 g/m ²	Size 130x110x185 mm (HxWxL)/outside measurements, white coating, 3-colour evercare printing
Transport carton	Carton, 395 g/m ² Corrugate paper; 3 ply, KI185/CA105/CA105	Size 280x197x345 mm (HxWxL)/outside measurements, brown, 1-colour evercare printing
Transport carton label	Coated paper	Size 210x120 mm, white, evercare printing
Packing tape	Transparent, PVC-free	

Quality Specifications of the Product

Characteristic	Target value	Tolerances	Test method reference
Construction	Product shall be intact	Product shall not disintegrate, split or tear when exposed to normal handling	Visual inspection

Product measurements and other details	see attached drawings	see attached drawings	Measuring
Cleanliness	No impurities allowed	No visible loose particles, dirt or dust (must be removed in production)	Visual inspection
Attachments of ties	Ties shall be firmly attached to filter media	Force for detaching tie from filter media: ≥ 16 N until breaking	In-house method by using tensile strength machine
Bacterial filtration efficiency (BFE)	---	≥ 98 %	EN 14683, Annex B.
Breathability (differential pressure)	---	$< 29,4$ Pa	EN 14683, Annex C

Manufacturing methods

Production stage	Requirements
Laying and cutting	Product must be cut to size which is defined in product drawings. Cutting must be neat.
Ultrasonic sealing	Upper, lower edges and ties
Machine folding	See separate folding instructions
Packing	See separate packing instructions

Description of the packaging system and labelling

REF	Unit pack	Dispenser	Carton
2865	-	50	300 (6 x 50)

Labeling information	See separate label specifications for labelling instructions
Shelf-life	3 years

Storage conditions: Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone

DECLARATION OF CONFORMITY

replaces version dated: 22.05.2015

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

declare under our sole responsibility that following products, all belonging to class I according to Annex IX of the Directive 93/42/EEC for medical devices,

Name, type or model:

2850	Surgical mask Multiguard, standard, blue
2851	Surgical mask Multiguard, standard, green
2852	Surgical mask Duckbill, blue
2853	Surgical mask, white
2854	Surgical mask Face shield, blue
2855	Surgical mask Multifix Starline, standard, blue
2856	Surgical mask Multifix, standard, green
2858	Surgical mask Multifix Guardline, standard, green
2859	Face mask Multifix Consumer, green
2860	Surgical mask Soft, Type II
2865	Surgical mask Multiguard Antifog, special, green
2875	Surgical mask Multifix Splash, extra, green
2876	Surgical mask, white
2877	evercare® Essentia Ergomask A, medical face masks with tie-bands, blue
2878	evercare® Essentia Ergomask B, medical face masks with ear-loops, blue

to which this declaration relates, are in conformity with the following harmonized standards or other normative documents

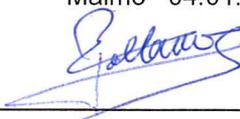
EN ISO 13485:2012	Medical Devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices
EN 14683:2014	Surgical masks – Requirements and test methods
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN 980:2008	Graphical symbols for use in the labelling of medical devices
EN ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

and with the provisions of the laws of Finland and with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of 5 September 2007.

Place and date of issue

Malmö 04.01.2017

Name and signature of the authorized person



Julien Rolland
Sourcing Director

DECLARATION OF CONFORMITY

replaces version dated: NA

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki,
SRN FI-MF-000000642,

declare under our sole responsibility that following products, all belonging to class I according to Annex VIII of the Regulation (EU) 2017/745 for medical devices,

Basic UDI-DI 6438129B0045HG

Item number (REF)	Trade and product name
2850	Surgical mask Multiguard, standard, blue
2851	Surgical mask Multiguard, standard, green
2852	Surgical mask Duckbill, blue
2855	Surgical mask Multifix Starline, standard, blue
2856	Surgical mask Multifix, standard, green
2858	Surgical mask Multifix Guardline, standard, green
2859	Face mask Multifix 10-pack, green
2875	Surgical mask Multifix Splash, extra, green
2877	evercare® Essentia medical face mask with tie-bands, blue
2878	evercare® Essentia medical face mask with ear-loops, blue
2881	evercare® Medical face mask with ear-loops, white, type IIR
2882	evercare® Medical face mask with ear-loops, white, type II
2883	evercare® Medical face mask with ear-loops, white, type II, 10-pack
2884	evercare® Medical face mask with tie-bands, blue, type IIR

Basic UDI-DI 6438129B0046HJ

Item number (REF)	Trade and product name
2853	Surgical mask, white
2854	Surgical mask, Face shield, blue
2860	Surgical mask, soft, type II
2865	Surgical mask Multiguard Antifog, special, green
2876	Surgical mask, white

to which this declaration relates, are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and with following European standards and common specifications¹:

EN ISO 13485	Medical Devices – Quality management systems requirements for regulatory purposes
EN ISO 14971	Medical Devices – Application of risk management
EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels – Part 1: General requirements

EN 1041	Information supplied by the manufacturer of medical devices
EN 62366-1	Medical Devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management
EN 14683	Medical face masks – Requirements and test methods

¹Latest applied revisions of regulations, standards and common specifications in *T-079 Review of regulations and standards*

Place and date of issue

Göteborg 24.05.2021

Name and signature of the authorized person



Martin Hillbratt

Quality and Regulatory Director
OneMed Group Oy