
		Technical Data Sheet	
Foliodress mask anti fogging			Spec.-No.: D 6.5531g
			Department: SM-PDO
			Date: 2016-11-10

1. General Product Description

Surgical face mask made of odorless nonwoven, with 3-layers; inner side white, outer side green, in - between a filter medium with a high bacterial filtration efficiency, nose piece and ties for fixation. Either side of the top edge of the mask is enveloped with a double strip of non permeable material.

Foliodress mask anti fogging carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for Foliodress mask anti fogging and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use and effectiveness of Foliodress mask anti fogging, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Surgical face mask for wearers with normal sensitive skin.
Especially suitable for wearers of glasses.



3. Presentations

In dispenser boxes, 50 pieces

Colour: green

4. Product Characteristics

Composition:	
Filter:	100 % polypropylene
Inner coverstock:	100 % polypropylene
Dimensions:	appr. 175 mm x 100 mm
Mask is latex and colophony free. Nose clip is nickel free.	

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5. Product Requirements

In conformance with EN 14683 : 2005 surgical masks requirements and test methods Product performance: Type II	
Bacterial filtration efficiency (BFE)	> 98 %
Differential pressure (Breathability)	< 29,4 Pa
Cleanliness – Microbial	< 30 CFU/g

6. Labelling

Lot-No. with 9-digit code:

e.g.:

1	023	XXXXX
year	serial production	for internal purposes

Expiry date: 5 years

7. Packaging

In dispenser boxes; packed into transport carton; transport carton acc. DIN, sealed with adhesitapes, packed onto europallet.

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i. A.



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