

		<h1>Technical Data Sheet</h1>
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<h2>Foliodress mask anti splash with visor</h2>		Spec.-No.:	D 6.5531f
		Department:	CMO-DOE
		Date:	2017-08-14

### 1. General Product Description

Surgical face masks made of odorless nonwoven, with 4-layers; inner side white, outer side blue, in - between a filter medium with a high bacterial filtration efficiency and a splash resistant layer on the outside of the mask, nose piece and ties for fixation. The visor shows inside and outside an anti fogging treatment. Large-area visor for eye-protection.

Foliodress mask anti splash with visor 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 splash with visor 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 splash with visor, therefore, is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication

Surgical face mask to cover mouth, nose and eyes in areas where splashes can occur. For wearers with normal sensitive skin.

### 3. Presentations

In dispenser boxes, 50 pieces

Colour: blue

### 4. Product Characteristics

Composition:	
Filter:	100 % polypropylene
Inner coverstock:	100 % polyester + cellulose

Low reflecting visor with anti fogging treatment

Mask Dimensions:	appr. 180 mm x 90 mm
Mask is latex and colophony free. Nose clip is nickel free.	

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### 5. Product Requirements

In conformance with EN 14683: 2014 Medical face masks - Requirements and test methods Product performance: Type IIR	
Bacterial filtration efficiency (BFE)	≥ 98 %
Differential pressure (Breathability)	< 49 Pa/cm <sup>2</sup>
Splash resistance pressure	≥ 16.0 kPa (120 mm Hg)
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.

Date: 2017-08-14

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