

<h2>Foliodress mask loop</h2>		Spec.-No.:	D 6.5531d
		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 or blue, in - between a filter medium with a high bacterial filtration efficiency, nose piece and elastic earloops for fixation.

Foliodress mask loop 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 loop 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 loop, 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.

### 3. Presentations

Article-No.	
<b>992 537</b>	Foliodress mask Loop, blue <b>Comfort</b>
<b>992 158</b>	Foliodress mask Loop, green <b>Comfort</b>

In dispenser boxes, 50 pieces

### 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.	

<h2>Foliodress mask loop</h2>		Spec.-No.:	D 6.5531d
		Department:	SM-PDO
		Date:	2016-11-10

### 5. Product Requirements

In conformance with EN 14683 : 2014 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.

Date: 2016-11-10

PAUL HARTMANN AG  
 CMO-Development OTM & Exam. Gloves (CMO-DOE)

i. A.



Dr. Henry Kutzt