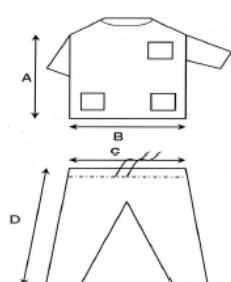


# Foliodress® Suit Protect, unsterile

## General Product Description/Intended Purpose

Foliodress Suit Protect are nonwoven suit 38 g/m<sup>2</sup> or 43 g/m<sup>2</sup> for operating room with shirt and pants. The shirt has short sleeves, a round collar doubled with a white nonwoven, one pocket on bottom of each side and one pocket on the left top. The pants have a waist belt. The available colors are blue, deep blue, green or purple.



Basis weight: 38 g/m <sup>2</sup>	XS	S	M	L	XL	XXL
A – Shirt's height (cm) (approximately)	69	71	74	76	78	80
B – Shirt's width (cm) (approximately)	50	53	57	61	65	70
C – Waist size (cm) (approximately)	47	51	55	59	63	67
D – Pants' height (cm) (approximately)	101	104	106	108	110	116

Basis weight: 43 g/m <sup>2</sup>	S	M	L	XL	XXL
A – Shirt's height (cm) (approximately)	71	73	76	78	79
B – Shirt's width (cm) (approximately)	52	56	61	64	70
C – Waist size (cm) (approximately)	51	54	60	63	67
D – Pants' height (cm) (approximately)	104	107	108,5	111	117,5

Intended Purpose: Foliodress Suit Protect are nonwoven suit intended to be used by healthcare professionals in clinical environment (operating room, interventional surgery department, other departments with significant infectious risk) to contribute to the control of the patient environment in order to limit infections.

Foliodress Suit Protect are class I medical devices.

## Application/Indication

Foliodress Suit Protect are worn by the medical staff to contribute to the control of the patient environment in order to limit infections: they can be used for any pathology and there is no contact with the patient.

## Reference Numbers

Color	Basis Weight	References XS	References S	References M	References L	References XL	References XXL
Blue	38 g/m <sup>2</sup>	992 605	992 538	992 539	992 540	992 541	992 542
Deep blue	38 g/m <sup>2</sup>	NA	992 543	992 544	992 545	992 546	992 547
Green	38 g/m <sup>2</sup>	NA	992 548	992 549	992 550	992 551	992 552
Purple	43 g/m <sup>2</sup>	NA	992 562	992 563	992 564	992 565	992 566

## Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

## Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Foliodress Suit Protect should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

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## Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

## Product Performance Characteristics

Nonwoven (standard performance)				
Property	Test method	Unit	Requirements of EN 13795-2	Test results
Resistance to dry microbial	ISO 22612	CFU	$\leq 100$	Conform
Particle release	ISO 9073-10	log10 (lint count)	$\leq 4,0$	Conform
Determination of the bursting strength	ISO 13938-1	kPa	$\geq 40$	Conform
Determination of the breaking strength and elongation – machine direction	EN 29073-3	N	$\geq 20$	Conform
Determination of the breaking strength and elongation – cross direction	EN 29073-3	N	$\geq 20$	Conform

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## Labelling

### Lot-No. with 9-Digit Code

e.g.:



AA

BBB

CC

DD

Order's year

Purchase order  
number

Supplier code

Serial warehouse entry  
number for raw material  
delivery

### or 7-Digit Code

e.g.:



YYY

X

ZZ

B

Calendar day  
of the  
production  
year

Production year

Workshop  
number

Letter for the production  
site

### Manufacturing Date

e.g.:



2015  
year

04  
month

07  
day

### Use-by-Date

e.g.:



2015  
year

04  
month

07  
day

Shelf Life: 5 years

### Medical Device



**Latest Date of Revision:** 22/01/2021