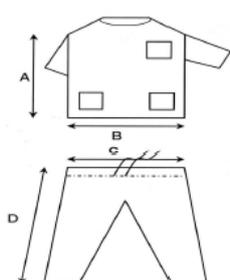


Foliodress[®] Suit Protect, unsterile

General Product Description/Intended Purpose

Foliodress Suit Protect are nonwoven suit 38 g/m² or 43 g/m² 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 ² | 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 ² | 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 ² | 992 605 | 992 538 | 992 539 | 992 540 | 992 541 | 992 542 |
| Deep blue | 38 g/m ² | NA | 992 543 | 992 544 | 992 545 | 992 546 | 992 547 |
| Green | 38 g/m ² | NA | 992 548 | 992 549 | 992 550 | 992 551 | 992 552 |
| Purple | 43 g/m ² | 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 | ≤ 100 | Conform | |
| Particle release | ISO 9073-10 | log10 (lint count) | ≤ 4,0 | Conform | |
| Determination of the bursting strength | ISO 13938-1 | kPa | ≥ 40 | Conform | |
| Determination of the breaking strength and elongation – machine direction | EN 29073-3 | N | ≥ 20 | Conform | |
| Determination of the breaking strength and elongation – cross direction | EN 29073-3 | N | ≥ 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