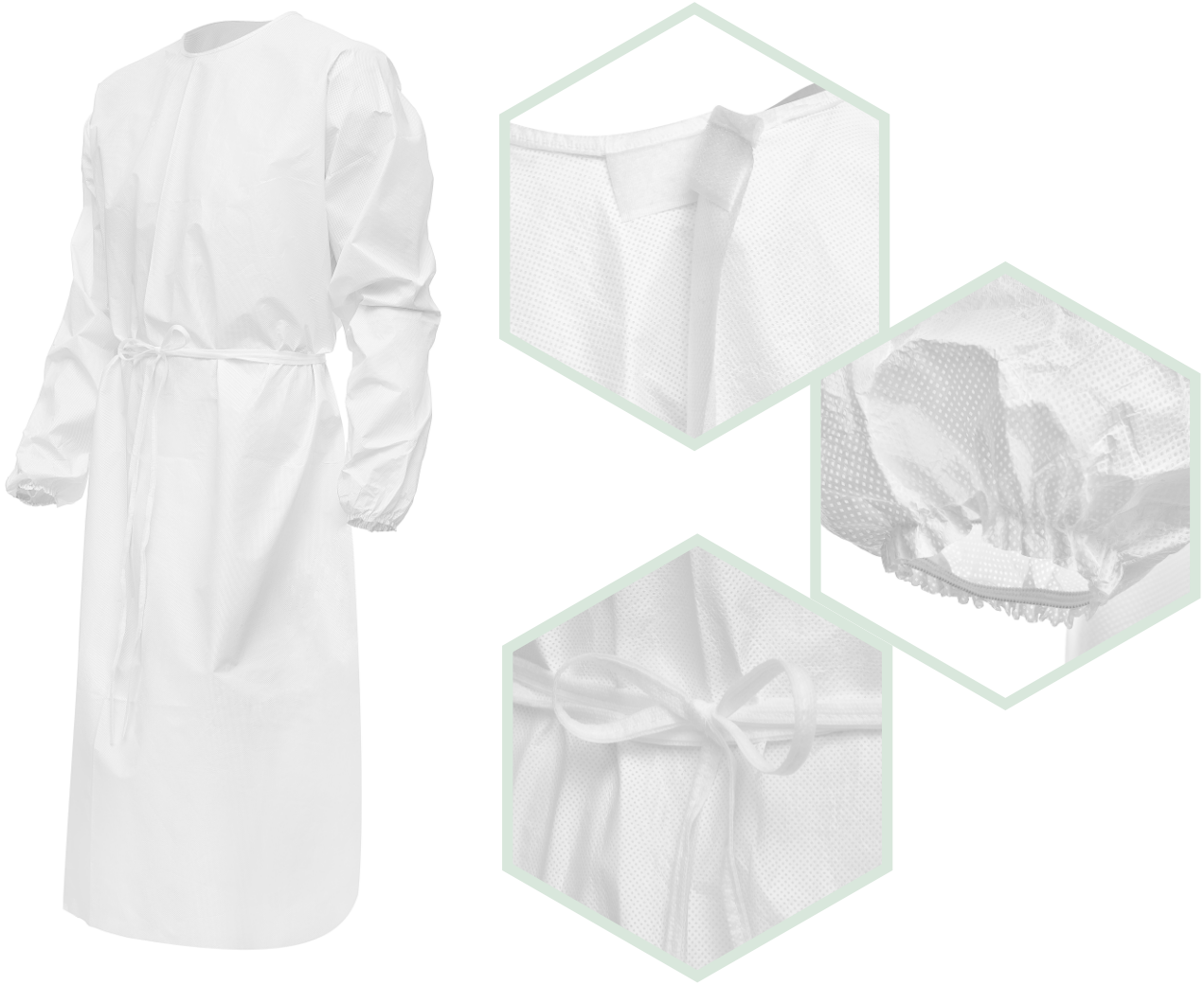
batist

immunity

PRODUCT INFORMATION SHEET



PROTECTIVE LAMINATED GOWN NON STERILE

REF	PRODUCT DESCRIPTION	SIZE	SINGLE PACK	TRANSPORT CARTON
1326002733	Protective laminated gown non sterile	S	10 pcs	80 pcs
1326002734	Protective laminated gown non sterile	M.	10 pcs	80 pcs
1326002735	Protective laminated gown non sterile	L	10 pcs	80 pcs
1326002736	Protective laminated gown non sterile	XL	10 pcs	80 pcs
1326002737	Protective laminated gown non sterile	XXL	10 pcs	80 pcs

COMMITTED TO SAFETY batist

www.batist.com

batist

immunity

PRODUCT TYPE: MEDICAL DEVICE IN CLASS I NON STERILE

PRODUCT NAME: PROTECTIVE LAMINATED GOWN NON STERILE

PRODUCT DESCRIPTION: Disposable protective gown made from PP / PE spundbond nonwoven laminate with a weight of 53 g /sqm, compliant with the requirements of MDD 93/42/EEC and EN 14126 (2003) + AC (2004) and certified with the Health Quality Certificate issued by the National Institute of Public Health - National Department of Hygiene.

MATERIAL: POLYPROPYLENE, POLYETHYLENE
MATERIAL TYPE: LAMINATE
COLOUR: WHITE

PRODUCT FEATURES:

- ✓ trimmed at the neck
- ✓ fastened with Velcro on the back
- ✓ tied at the waist with a 3-meter string made of trimming, attached in the front of the apron
- ✓ elastic band is sewn in the lower part of the sleeves
- ✓ non sterile
- ✓ for single use only

SPECIFIC MATERIAL AND CONSTRUCTION FEATURES

The gown is made from non-woven-foil laminate, which provides a very high level of breathability while ensuring a sufficient level of barrier to aerosols and infectious agents.
The seams of gown are moved to the rear part to ensure maximum protection in the front part of gown.

TEST RESULTS

The unique properties of such material allowed to obtain positive test results in accordance with EN 14126: 2003 + AC: 2004 standard, and health quality certificate issued by the National Institute of Public Health - National Institute of Hygiene

SAFETY PROPERTIES AND ADVANTAGES

This product , thanks to meeting the requirements of EN 14126 - "Protective clothing. Requirements and test methods for protective clothing against infectious agents", can replace protective coverall in places and among personnel with a lower level of exposure to COVID-19 (e.g. wards and staff with occasional or unforeseen contact with an infected patient, laboratories, private clinics and outpatient clinics, private medical practices.

Due to the fact that design of gown makes it easier and safer to remove it after use, this reduces the risk of accidentally infecting the user during this process.
This gives this product a significant advantage over coverall, obviously in the case of using this apron by staff who are not obliged to use only coverall due to the specifics of the ward, work and patients.

COMMITTED TO SAFETY batist

www.batist.com

batist

immunity

QUALITY TEST RESULTS OF PRODUCT

In accordance with applicable law, finished product was tested in an independent, accredited laboratory for compliance with the standards provided for these products. The table below presents results of these tests, compiled with normative requirements, and numbers of test protocols.
At the customer's request , we are able to provide the results of research.

EN 13795-2:2019 Surgical clothing and drapes – Requirements and test methods -

Part 2: Clean air suits

Table 1 — Characteristics to be evaluated and performance requirements for clean air suits

Characteristic	Test method (for normative references see Clause 2)	Unit	Requirement		Test results		Testing protocol No.
			Standard performance	High performance	Standard performance	High performance	
Microbial penetration — Dry	EN ISO 22612	CFU	≤ 100	≤ 50	**< 1**	**< 1**	140b/1/BME/2020
Cleanliness microbial / Bioburden	EN ISO 11737-1	CFU/ 100 cm^2	≤ 100	≤ 100	**27**	**27**	128/1/BME/2020
Particle release	EN ISO 9073-10	log_{10}(lint count)	≤ 4,0	≤ 4,0	**1,64**	**1,64**	140a/1/BME/2020
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	**64,0**	**64,0**	BM 731.1/2020/B/A
Tensile strength — Dry	EN 29073-3	N	≥ 20	≥ 20	**106,0**	**106,0**	BM 731.1/2020/B/A

COMMITTED TO SAFETY batist

www.batist.com

batist

immunity

INTENDED USE: Product is intended for personal protection against contamination in health care facilities, hospitals, etc.

SHELF LIFE: 5 years

REGULATIONS:

REACH REGULATION: The product covered by this data sheet does not contain carcinogenic, mutagenic or toxic substances, including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).

LEGAL REQUIREMENTS: Medical Device Directive 93/42/EEC, class I non sterile

BIOLOGICAL EVALUATION: EN ISO 10993-5; EN ISO 10993-10

QUALITY STANDARDS: EN ISO 13485:2016: EN 14971: 2020

PRODUCT STANDARDS: EN 14126: 2003 + AC: 2004; EN 13795-2

LABEL SYMBOLS:

STORAGE RECOMMENDATION: Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone

DISPOSAL RECOMMENDATION: Follow local instructions

COMMITTED TO SAFETY batist

www.batist.com