



Ficha Técnica

BATA DE PROTECCIÓN CONTRA AGENTES BIOLÓGICOS

Identificación de la empresa

Razón social DISTRAUMA MEDICAL, S.L.
NIF B-61435079
Fabricante/ Distribuidor Distribuidor

Datos del producto específicos

Referencia 422497738
Marca comercial Distrauma Medical

DESCRIPCIÓN	Bata de protección con tejido de polipropileno, con revestimiento en toda la superficie de la bata, cintas en cintura y cuello y puños de algodón en las mangas. No estéril, de un solo uso.
FOTOGRAFÍAS	
MATERIALES UTILIZADOS	Fabricada con tejido de polipropileno hilado, 22 g / m ² Recubrimiento PE (20g / m ²)
CARACTERÍSTICAS	Medidas: 139 x 139 cm Color: azul
PRESENTACIÓN	100 unidades
CONSERVACIÓN	Almacenar en lugar seco a una temperatura entre 10°C y 25°C, mantener alejado de radiadores y/o puertas de almacén y de la luz directa del sol.
CERTIFICADOS	EPI certificado de Clase III según el Reglamento (UE) 2016/425 EN ISO 14126/03 + AC / 04 Tipo PB-6B     



EU TYPE-EXAMINATION CERTIFICATE

No **CE 1327200656 -00 - 02**

According to "Regulation (EU) 2016/425 of the European Parliament and of the Council" of 9th March 2016 on Personal Protective Equipment and repealing Council Directive 89/686/EEC

Centro Tessile Cotoniero e Abbigliamento S.p.A.
P.zza Sant'Anna, 2 - 21052 Busto Arsizio (VA) - Italia

EEC Notified Body N° 0624

- in view of the firm's application submitted on: 16th February 2021;
- in view of the positive results of the Technical File verification submitted by the manufacturer together with the above mentioned request;
- in view of the manufacturer's declaration stated in the Technical File attached to the above mentioned request
- having verified that technical specification of design and manufacture is in compliance with basic requirements specified in annex II of Regulation (EU) 2016/425 and that technical manufacturing documentation is in compliance with above mentioned specifications;
- in view of the positive test results carried out on the basic model representative of production according to paragraph 4 of annex V of Regulation (EU) 2016/425;

Issues to:

NORDISKA GMBH & CO. KG
Victoria Hohe 1, 51645 Gummersbach, Germany

the EU Type-Examination Certificate concerning the following PPE model:

NONWOVEN PROTECTIVE GOWN

cod. **97738**

Category: **III** (third)

The model of Personal Protective Equipment is subject to conformity to type assessment according to Section 19 c) of Regulation (EU) 2016/425 (Module C2 or D)



Basic type description

Isolation Gown cod. 97738



Variations description

Variation with knitted cuffs

Sizes

One size

Standards

EN ISO 13688:2013	Protective clothing - general requirements
EN 14126:2003 +AC:2004 Type PB 6-B	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

Performance levels

EN 14126	Class 6	Resistance to penetration by contaminated liquids under hydrostatic pressure.
	Class 6	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.
	Class 3	Resistance to penetration by contaminated liquid aerosols.
	Class 3	Resistance to penetration by contaminated solid particles

Tests

The test results are included in the report: 20RA07847, 20RA07850, 20RA11173

Marking



The following information are listed on the label inside the garment:

- CE marking
- Company name
- Article code
- Standards
- Standardized pictograms
- Maintenance symbols
- Fabric composition
- PPE category

Validity

- This certificate has 5-year validity from issue date. On expiration date the Manufacturer will be responsible to require the renewal.
- Any change on model and materials object of this Certificate shall be notified and then approved by Centrocot.

This certificate must be filed by the manufacturer and must be shown, if requested, to the Body that performs controls or to the surveillance authority

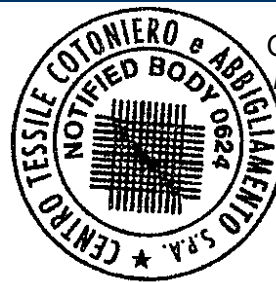
Busto Arsizio,

Issue date:
07th October 2020

Rev 01 date:
10th December 2020

Rev 02 date:
17th February 2021

Expiry date:
07th October 2025



General Manager
Dr. Grazia Cerini

EU Declaration of Conformity according to the PPE regulation (EU) 2016/ 425

The manufacturer:
Nordiska GmbH & Co. KG
Victoria height 1
51645 Gummersbach
Germany

declares on its own responsibility that
Article
97738 Isolation gown (PP with PE coating)

Is conform to Regulation (EU) 2016/ 425 and complies with the harmonised standards:

EN ISO 14126:2003+AC:2004	EN ISO 13688:2013
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This product is PPE of category III according to Annex I of the Regulation and is identical to the PPE covered by the EU Type Examination Certificate No. CE 1327200656-00-00 issued by Centrocot (identification number 0624)

and is subject to the procedure according to module C2 of Regulation (EU) 2016/ 425 under the control of the notified body Centrocot (identification number 0624).

Technical documentation meeting the requirements is available as proof.

Gummersbach, 07.10.2020



Dag Pfeiffer, CEO

This declaration of conformity is valid until 07.10.2025



CENTROCOT
Innovation experience

NORDISKA GMBH & CO. KG

Victoria Hohe 1, 51645
Gummersbach, Germany

Busto Arsizio, 25th February 2021

Object: **NONWOVEN PROTECTIVE GOWN**
cod. **97738**

Hereby we declare

that the PPE model Isolation Gown cod. 97738

EC type certificate n 1327200656-00-02 issue date 07th October 2020, expire date 07th October 2025;

is under quality control system for the final product according to REGULATION (EU) 2016/425 Module C2 by Centro Tessile Cottoniero & Abbigliamento, Notified Body n. 0624.

Best regards

Marco Colli
PPE Testing and Certification Manager