

FICHA TÉCNICA

Ref. VDE005



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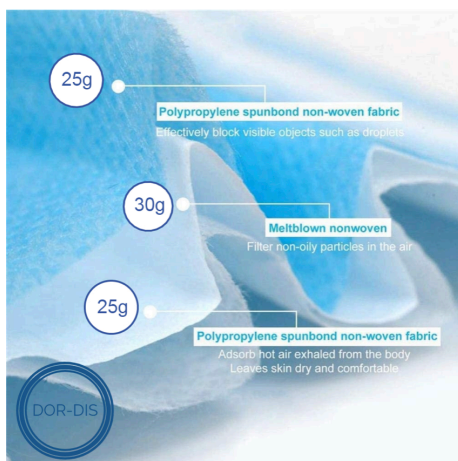
-MASCARILLA QUIRÚRGICA TIPO 2

-Reutilizable hasta 5 lavados.

- **Primera capa de 25g** de spandbond de polipropileno textil no tejido con tratamiento hidrofóbico, (no permite la penetración de líquidos).
- **Segunda capa de 30g** de textil de polipropileno no tejido con tratamiento hidrofóbico de spandbond.
- **Tercera capa de 25g** de textil de polipropileno no tejido con tratamiento hidrofóbico de spandbond.

FABRICACIÓN Y DISTRIBUCIÓN

Dor-dis ofrece a sus clientes paquetes de 50 unidades. La producción es constante, por tanto no tenemos limite de stock. Nuestra fabrica produce bajo certificado UNE-EN-14683 que asegura una calidad hospitalaria tipo II y un nivel de filtración bacteriana del 99,9%.



CARACTERÍSTICAS

Las máscaras garantiza una excelente filtración antibacteriana. Cada capa está hecha de polipropileno (no tejido), con diferente espesor y densidad.

Están equipadas con dos gomas elásticas que se adhieren con comodidad a las orejas. Captura partículas segregadas (saliva, secreciones,etc.) al mismo tiempo que no dificulta la respiración del usuario . Libre de látex, fibras de vidrio y más alógenos.

Frimsal Distribuciones, S.L.

Avda. Canaletes, 45 - 08290 Cerdanyola (Barcelona)

C/ La Ventilla, 37 - 41620 Marchena (Sevilla)

Telf. 902 125 661 - Fax. 902 102 156 - E-Mail; info@frimsal.es

<http://www.frimsal.com>

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БИОЛОГИЧЕСКИ ФАКУЛТЕТ



SOFIA UNIVERSITY
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FACULTY OF BIOLOGY



PROTOCOL № 38-1/26.05.2020

of virological testing of a medical mask

Article: A three-layer disposable medical mask DD01/20, 5 samples

Article material:

- first layer of 25 g nonwovens spunbond polypropylene with hydrophobic treatment;
- second layer 30 g filter non-woven textile meltbond polypropylene;
- third layer 25 g nonwovens spunbond polypropylene.

Manufacturer: DOR - DIS LTD., 1 Iskra Str., Pazardzhik 4400, Bulgaria

In the laboratory "Virology", Faculty of Biology at Sofia University "St. Cl. Ohridski" e is tested a three-layer medical mask, made of nonwovens spunbond and meltbond polypropylene of company DOR - DIS LTD. in accordance with the scope of EN 14683:2019+AC.

The mask is treated once in a sterile environment, in sterile vacuum apparatus with pre-placed plates with a specific coating to capture viral particles. The treatment is carried out in the form of an aerosol, which contains a human virus with a high concentration to moisten the surface of the studied objects. Viral particles are similar in size to coronaviruses. Subsequently, a suction with a capacity of 20 millibars is applied. The coating is treated with cell culture medium, after which the medium is inoculated into microplates with a cell monolayer.

After 48 hours of culturing at 37°C, no viral cytopathic effect was visually detected in the samples from the mask treatment which was also confirmed by the lack of viral titer. The amount of virus detected in the control sample corresponded to the baseline

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**PROTOCOL № 38-2/26.05.2020****of Bacterial Filtration Efficiency and Differential Pressure testing of medical mask**

Article: A three-layer disposable medical mask DD01/20, 5 samples

Article material:

- first layer of 25 g nonwovens spunbond polypropylene with hydrophobic treatment;
- second layer 30 g filter non-woven textile meltbond polypropylene;
- third layer 25 g nonwovens spunbond polypropylene.

Manufacturer: DOR - DIS LTD., 1 Iskra Str., Pazardzhik 4400, Bulgaria

The procedure was performed to determine the bacterial filtration efficiency (BFE) of the filtration materials, employing a ratio of the bacterial challenge counts to test article effluent counts to determine percent bacterial filtration efficiency (%BFE). This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This method complies with ASTM F2101/ EN 14683 Annex B.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of porous materials. The technique involved a simple application of a basic physical principle employing a manometer differential upstream and downstream of the test material, at a constant flow rate. This method complies with EN 14683 Annex C.

Test side: Outside

Area tested: ~75 mm diameter

BFE Flow Rate: 28.3 L/min

Delta P Flow Rate: 8 L/min

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Results:

Test Article	Percent BFE (%)	Delta P (Pa/cm ²)
01	>99.9*	37.26
02	>99.9*	38.25
03	>99.9*	35.30
04	>99.9*	40.00
05	>99.9*	38.25

* There were no detected colonies on any of the Andersen sampler plates for this test article.

Mean Positive Control Count: 2,552 colony forming units (CFU)

Negative Control Count: <1 CFU

Mean Particle Size: 3.0 µm

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PROTOCOL № 38-3/26.05.2020

of Microbial Cleanliness (Bioburden) testing of medical mask

Article: A three-layer disposable medical mask DD01/20, 5 samples

Article material:

- first layer of 25 g nonwovens spunbond polypropylene with hydrophobic treatment;
- second layer 30 g filter non-woven textile meltbond polypropylene;
- third layer 25 g nonwovens spunbond polypropylene.

Manufacturer: DOR - DIS LTD., 1 Iskra Str., Pazardzhik 4400, Bulgaria

The testing was conducted in accordance with EN 14683:2019+AC, with bottle size, approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a validated software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms.

Results:

Test Article	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
01	74.4	9*	15	14.8	0.2
02	74.6	9*	6	14.7	0.2
03	74.4	9*	15	20.1	0.3
04	75.3	12*	3	14.8	0.2
05	73.2	17*	3	23.7	0.3

Note: The results are reported as colony forming units (CFU) per mask.

Note: Sample positive testing was performed using *Bacillus atropheus*.

*Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.

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Procedure:

Positive Controls/Monitors: *Bacillus atrophaeus*

Extract Fluid: Peptone Tween® with Sodium Chloride

Extract Fluid Volume: ~600 mL

Extract Method: Orbital Shaking for 5 minutes at 250 rpm

Plating Method: Membrane Filtration

Agar Medium: Tryptic Soy Agar

Sabouraud Dextrose Agar with Chloramphenicol

Aerobic Bacteria: Plates were incubated 3 days at 30-35°C, then enumerated.

Fungal: Plates were incubated 7 days at 20-25°C, then enumerated.

CONCLUSION:

The article complies with Class I, Type II.

The provided three-layer medical mask protects 100% of viruses the size of SARS-Co-2 when inhaling aerosols containing them. Mask is for single-use.

26.05.2020

Signature:



/ Prof. Dr. St. Shishkov/

EC DECLARATION OF CONFORMITY

The declaration of conformity is issued solely under the responsibility of the manufacturer.

The undersigned, representing the manufacturer

Dor-Dis LTD, Bulgaria, Pazardzhik 4400, 1 Iskra Str.

Hereby declares that the product covered by this Declaration,

A THREE-LAYER DISPOSABLE MEDICAL MASK

CE DD01/20, UMDNS код 12447, Category 10 – Single-use devices, Class I, type II



complies with relevant harmonized legislation of the European Union:

DIRECTIVE 93/42/EEC of 14 June 1993;

STANDARD EN 14683:2019+AC:2019.

The product is with certificate № **CE20052122** from 21.05.2020r, issued by TQV Certification Services Pvt. Ltd.

Pazardzhik
26.05.2020

Signature and stamp:
Zhana Aleksandrova, Manager






CE

CERTIFICATE

The company

Extrapack OOD
Kozludzha Str. 1A
5000 Veliko Tarnovo, BULGARIA

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report **19.0.83271**



for the following articles:

Non-woven fabric made of 100 % polypropylene in colours white, beige, light blue and black.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 4, **product class I** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 4 for baby articles.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate 16.HBG.89637 is valid until 30.09.2020

Boennigheim, 19.08.2019


Dipl.-Ing. (FH) Ivonne Schramm
Leiterin Zertifizierungsstelle OEKO-TEX®

OEKO-TEX® Association | Genferstrasse 23 | P.O. Box 2006 | CH-8027 Zurich

