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NanoMask Project

NanoMask - Development of thermoformed FFP2 masks, using a filter with a filtering capacity gradient (nano/micro) for use in a professional context.

Sponsor:	Poleva
Partners:	Fibrenamics (TecMinho)
Acronym:	NanoMask

NanoMask Project

At NanoMask project, a light mask composed of a multilayer system with an extra component to increases the support and comfort was produced. This new technology combines the three most important topics – effectiveness, comfort and sustainability.

The developed mask has the following technical features:

- FFP2 level;
- A biodegradable component;
- Design that increases respiratory comfort;
- Produced by thermoforming;
- Lightweight.

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Development strategy

The NanoMask was developed and further characterized in order to obtain a mask with an FFP2 protection level.

So, the study comprised some steps to ensure that the mask fulfils the defined requirements, either in terms of functionality as well as in terms of design and comfort. This study general steps were:

- Characterization of the materials that compose each layer;
- Optimization of thermoforming parameters;
- Study of the obtained multilayer system.

Together with the above-mentioned steps, the study of the design of the mask was carried out to produce an ergonomic mask.

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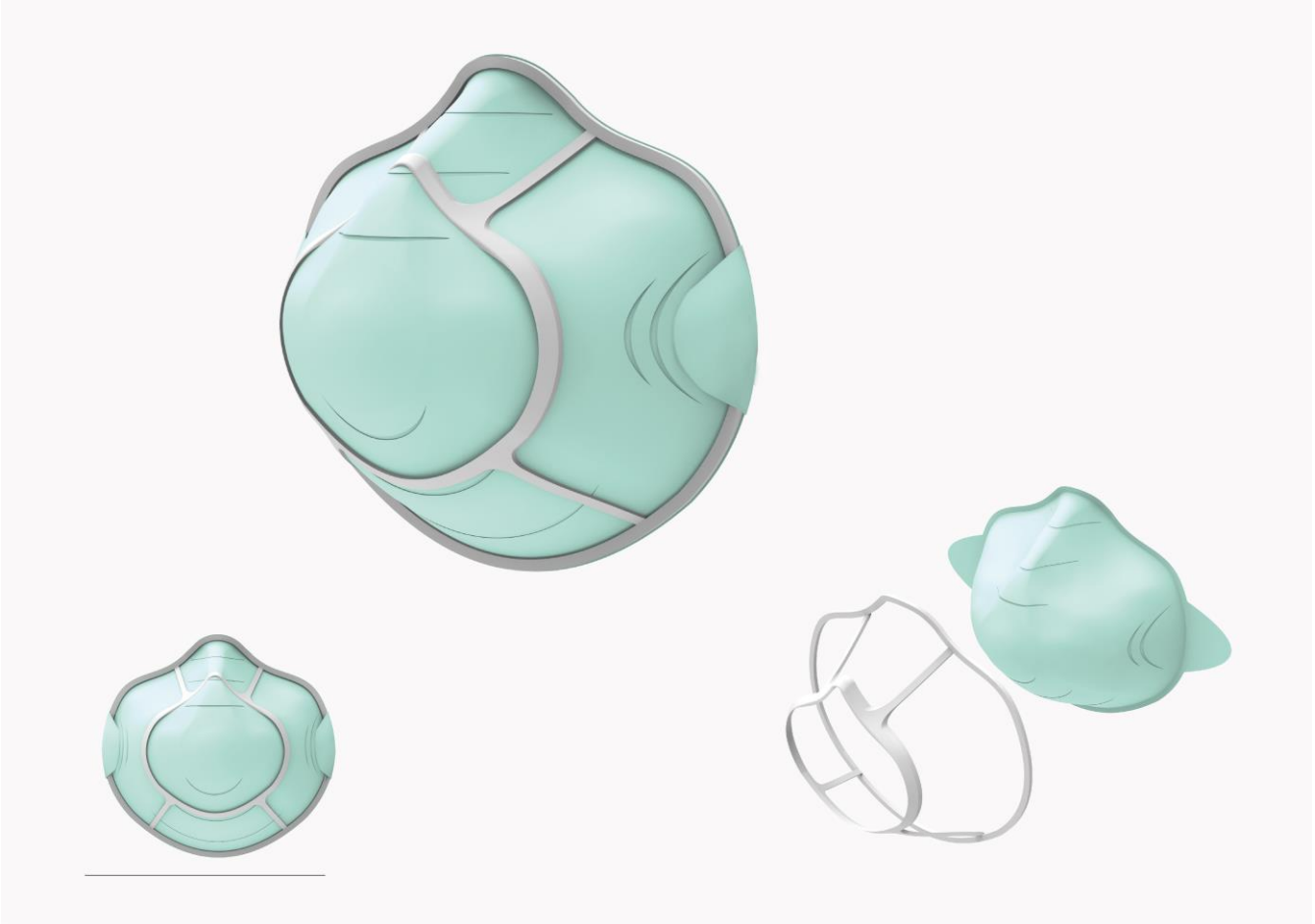
Design of NanoMask

The design of NanoMask was studied in order to produce a mask with high levels of comfort. The points developed in this study were:

- Ergonomic shape - anthropometric measurements of the population were considered in the development of the concept;
- More comfortable elastic fitting - an innovative system that aims to circulate the elastic on the sides of the mask, exerting less pressure on the user and therefore being more comfortable;
- Increased respiratory comfort by expanding the volume of the breathing chamber;
- An extra reusable structure added to the mask to increase the mask' support. Also, this structure increases the comfort since it helps at the fitting between mask and face, increasing the breathability comfort, and has an important role for people who wear glasses because do not allow them to fog up. This structure is produced with a biodegradable polymer and is extra light.

Design of NanoMask

The resulting technical drawing of the mask obtained from the study mentioned on the previous slide is here represented.



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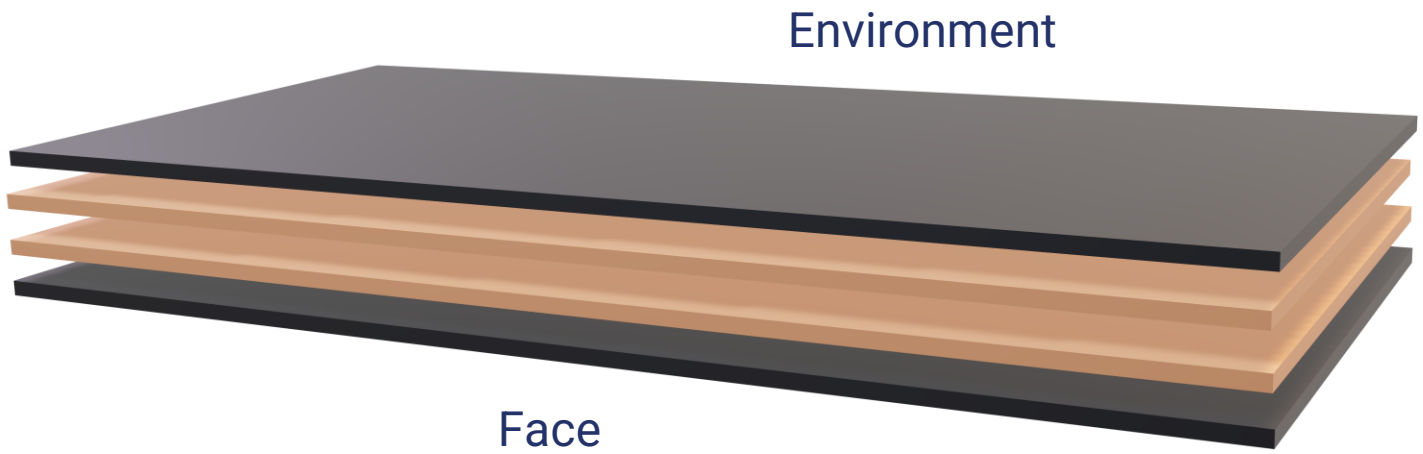
The multilayer system

To build up the concept previously presented is important to study the materials that will compose it, as well as its combinations.

The nonwovens that compose the mask were acquired at Freudenberg Filtration Technologies SE & Co and its fibres are made of polypropylene polymer. With these nonwovens, a multilayer system was made with the schematization below represented.



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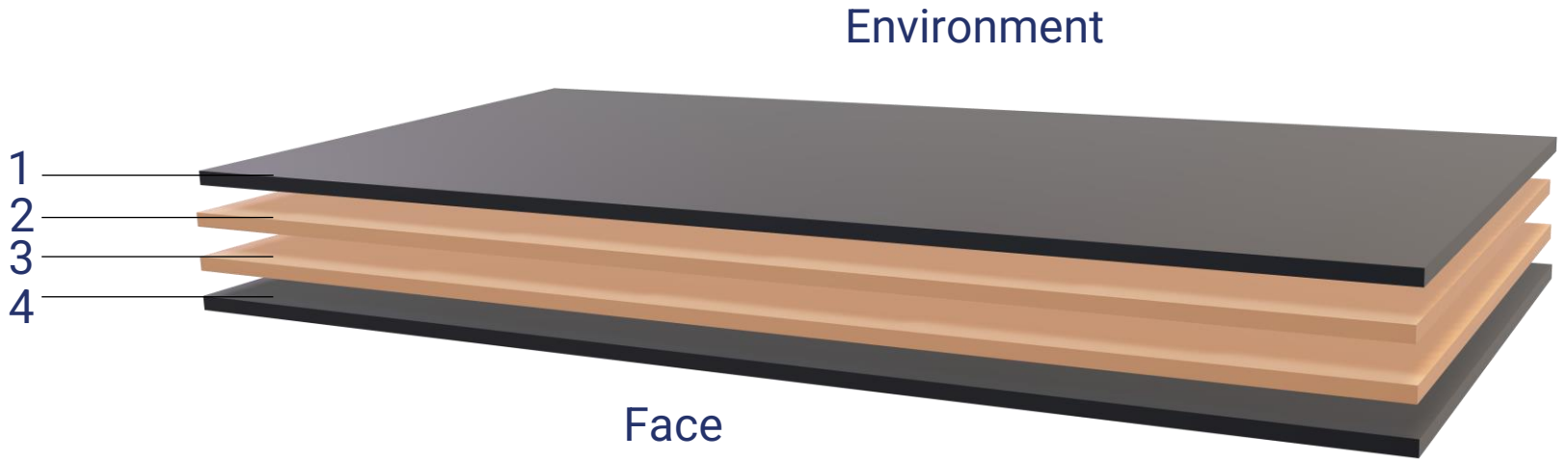
The multilayer system



Spunbond layer

Meltblown layer

Membrane's properties before thermoforming process:

Layer	Polymer	Average diameter (µm)	Average pore size (µm)	Average pore percentage (%)	Air permeability ($l/m^2/s$)	Weight (g/m^2)
1	Polypropylene	26.47 ± 2,21	554.72	25.85	1050.0	40
2		2.91 ± 1,41	56.67	10.16	42.3	50
3		2.92 ± 1,40	51.61	8.56	54.2	40
4		26.67 ± 2,53	790.98	32.01	3300.0	20

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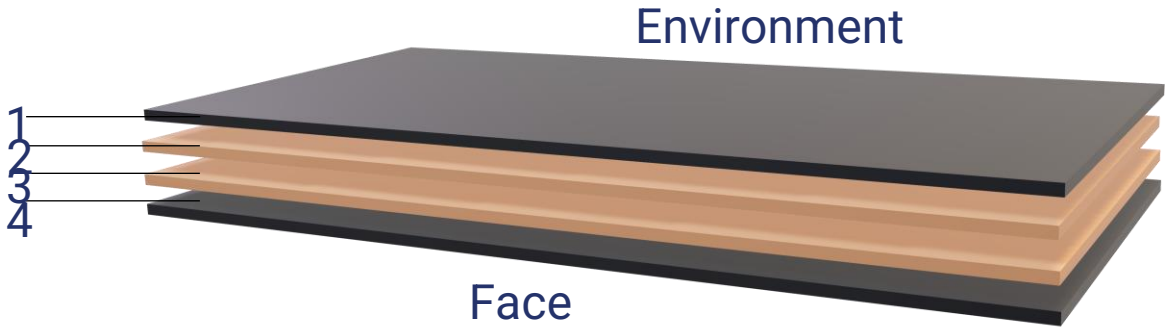
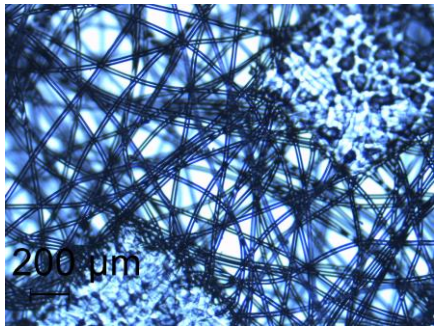
The multilayer system



Each membrane was microscopically studied. The obtained images are here represented. It was observed that all membranes have their fibres randomly oriented. Also, the outer and inner layers have more empty spaces. On the other side, the filtration membranes have more fibre per unit of area. These results follow the ones presented in the previous slide.

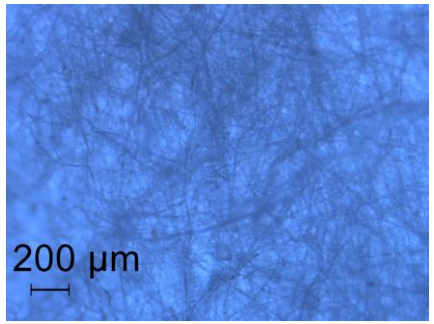
Outer layer

1 in the scheme

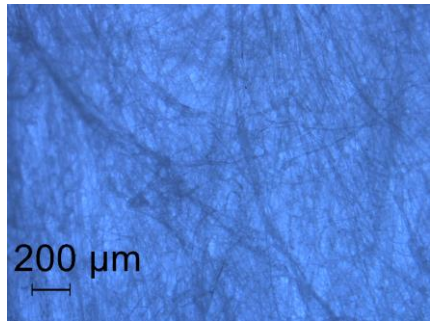


Filtration layers

2 in the scheme

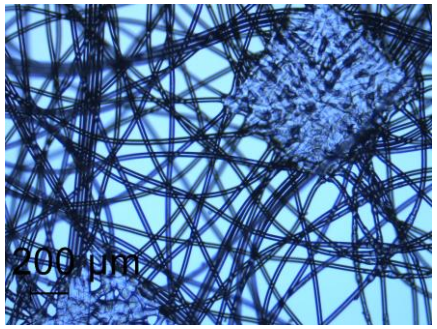


3 in the scheme



Inner layer

4 in the scheme



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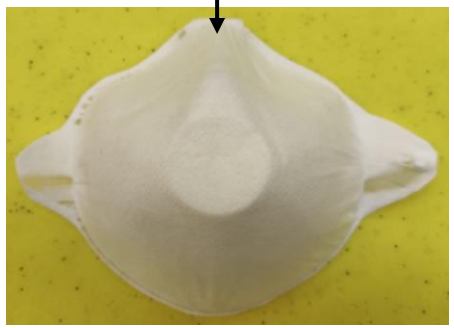
The multilayer system

From the results presented in the 2 previous slides is possible to conclude that:

- The fibres that compose the filtration layers – layers 2 and 3 – have smaller diameters, are denser and have a smaller pore size and distribution. These topics are very important to increase the filtration performance since it increases the capability to retain the particles to be filtered;
- The membranes have a low weight which will decrease the weight of the final structure – mask.

The Thermoforming process

The membranes previously studied were combined to obtain a multilayer system with high filtration rates. The thermoforming was the applied process to combine the several membranes. So, it was important to optimize its processual parameters to ensure that the several layers stay perfectly attached by the edges of the mask without compromising the polymeric fibres integrity. The temperature, the time and the mask mould were the studied parameters.



To optimize the mask mould, the mask design study was considered, as well as the fibres' behaviour with the temperature and pressure applied.

The optimized temperature was 125°C applied for 90 seconds.

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The Thermoforming process

After thermoforming process optimization, it was possible to produce NanoMasks on a high scale. Bellow, some produced masks are represented. The obtained mask are very light.

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NanoMask certification

The filtration performance of the obtained structure was studied by Aitex textile research institute, to ensure that the masks fulfil the FFP2 masks specifications. After this confirmation, the masks were certified by this entity according to the Rfu PPE-R/02.075.02 regulation.

aitex
textile research institute

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NanoMask certification

Within these certification, the practical behaviour of the mask was studied and evaluated by PASS or NOT PASS. The evaluated topics are specified below and all of them had the evaluation PASS. The conditions applied are also referred.

Tested parameters	Conditions 1	Conditions 2
Fitting of the mask on the user	Walk for 10 minutes at a speed of 6 km / h	Walk for 5 minutes at a free height of 1.3 ± 0.2 m; Crawl for 4 minutes at a free height of 0.7 ± 0.05 m; Filling a 1.5 hopper approximately 20 times.
The material should not irritate the skin		
Easy placement and removal		
Don't compromise the user's vision		
Good sealing of the mask on the face		

NanoMask certification

The filter's performance was studied by the evaluation of the filter penetration using sodium chloride particles. The obtained results are presented below.

Sodium chloride penetration teste (3.5 minutos)
Average value of penetration (%)
0.18

Exposure to 120mg of sodium chloride
Maximum value of penetration
0.3

According to the legislation, the maximum penetration of sodium chloride into the filter must not exceed 6 % to be categorized as an FFP2 mask.

The obtained results (0.18%) are under these specification, so, in terms of filter performance the mask was approved.

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NanoMask certification

The breathability parameters were also evaluated. Firstly, the average value of CO_2 in inhaled air was measured. This value should not exceed an average of 1% to be accepted as FFP2 mask. The obtained results follow this requirement.

Average value of CO_2 in inhaled air (%)
0.51

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NanoMask certification

In the end, the breathing resistance was also evaluated, either in terms of inhalation and exhalation.

At resistance to inhalation all obtained results are following the ones defined to be approved as FFP2 masks since the resistance to inhalation at 30 l/min was lower than 0.7 mbar and at 95 l/min was lower than 2.4 mbar.

Resistance to inhalation at 30 l/min (mbar)	Resistance to inhalation at 95 l/min (mbar)
0.50	1.99

At resistance to exhalation evaluation, according to the regulation, all values should be below 3.0 mbar. Once more, it was observed that the obtained results follows the ones defined by the regulation.

Resistance to exhalation(160 l/min) mbar					
Amostra	Forward	Upwards	Down	Towards the left side	Towards the right side
1	2.98	2.98	2.99	2.99	2.99

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NanoMask certification

Since all the results previously presented are under the ones defined by regulation, the NanoMask was certified as an FFP2 mask. It is important to emphasize that generally, all values are below the defined threshold value with a wide range. These results prove the high performance of the applied materials as well as suitable optimization of the processual parameters.

In the next slides some copies of documents that prove this certification are represented.

NanoMask certification

POLEVA Termoconformados, S.A. CE 0161
Rua da Estrada, nº 1939 - 4610-744 Sendim FLG - Portugal

NanoMask 16C sem valvula

Este producto ha sido fabricado de conformidad con el Reglamento (UE) 2016/425, para uso básico, PPE-R / 02.075 VERSIÓN 2 Dispositivos de protección respiratoria. Medias máscaras filtrantes para proteger solo para COVID 19. Requisitos, pruebas, marcado, de conformidad con el certificado nº 0161 / xxxx / aa **por AITEX**, Plaza Emilio Sala nº 1, Alcoy, España, organismo notificado 0161

Recomendaciones de uso:

El EPI se fabrica en un material no tejido con:

La máscara consta de una tela no tejida termoplástica multiescala. El soporte y ajuste es una estructura biodegradable que puede ser reutilizable para 5 filtros.

Advertencias
-Esta máscara está fabricada solo para protección COVID 19.

ajuste de media máscara filtrante;
Cada embalaje será controlado antes de ser lacrada.

- Es poco probable que se cumplan los requisitos de fugas si el vello facial pasa por debajo del sello facial;
- Máscara no válida en condiciones de baja calidad del aire (contaminantes, deficiencia de oxigeno);
- Máscara no válida en atmósferas explosivas
-este producto no es resistente a las llamas y no debe usarse en áreas con llamas abiertas
-El usuario debe conocer el uso y manejo de la máscara.
-No utilizar zonas de riesgo de explosión.

*Esta media máscara filtrante está fabricada solo para protección COVID-19. Según lo solicitado por las recomendaciones de la Organización Mundial de la Salud, para este uso específico, el factor de protección nominal proporcionado por esta media máscara filtrante es el mismo que el factor de protección nominal FFP2 definido en EN 149: 2001 + A1: 2009. Esta media máscara filtrante no es una media máscara filtrante para uso general y no debe usarse para fines distintos a la protección contra COVID-19 *.

Obtener niveles

VALOR OBTENIDO: PASA

Máxima penetración del material del filtro:

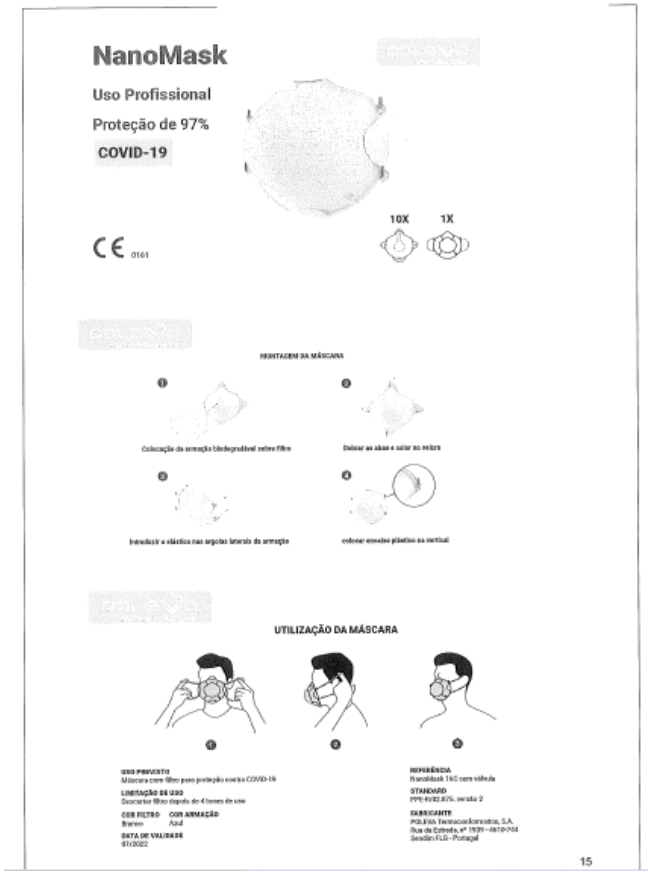
Clasificación	95 l/min % Max.
FFP2	6

El nivel FFP2 es un parámetro guía de la norma EN 149: 2001 + A1: 2009, no aplicable para RIU PPE-R / 02.075 VERSIÓN 2 ya que la validez final para el método de certificación COVID 19 es de acuerdo con un PASS / NOT PASS.

Almacenamiento: Mantenga la prenda alejada de la exposición innecesaria a la luz solar, en lugares secos y protegida contra agentes agresivos.

Embalaje: 1 kit (10 mascarillas)

Web: Declaración de conformidad
WWW.poleva.com/NanoMasK
Esta página web será publicada así que se emita el certificado.



ANEXO VI: DECLARACIÓN DE CONFORMIDAD

DECLARACIÓN DE CONFORMIDAD

El fabricante establecido en la CE:
POLEVA Termoconformados, S.A.
Rua da Estrada, nº 1939 - 4610-744 Sendim FLG - Portugal

Emite esta declaración de conformidad, bajo su exclusiva responsabilidad y declara que el EPP descrito a continuación:

NanoMask 16C sem valvula

It complies with the provisions of the EU Regulation 2016/425 of March 9, 2016 and, in
particular, with the specifications of the harmonized standards: PPE/R02.075.02 edited by the European Committee for Standardization.

Cumple con las disposiciones del Reglamento de la UE 2016/425 del 9 de marzo de 2016 y, en particular, con las especificaciones de las normas armonizadas: PPE/R02.075.02 editadas por el Comité Europeo de Normalización.

The Notified Body ASSOCIATION OF RESEARCH OF THE TEXTILE INDUSTRY, notified body nº0161, in Plaza Emilio Sala 1, 03801 Alcoy, Alicante, has carried out the EU type examination (module B) and
has issued the EU type XXXX / XXXX / XX certificate.

El organismo notificado ASOCIACIÓN DE INVESTIGACIÓN DE LA INDUSTRIA TEXTIL, organismo notificado nº0161, en Plaza Emilio Sala 1, 03801 Alcoy, Alicante, ha realizado el examen de tipo UE (módulo B) y ha emitido el certificado de tipo UE XXXX / XXXX / XX.

Hecho en 17/06/2021 Fecha Felgueiras

Firmado

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Conclusions

Through this study, it was possible to produce a new type of mask that is very light and can retain a higher percentage of particles such as viruses. Also, the masks have an extra component that increases comfort and is composed of sustainable materials. This mask increases the portfolio present in the market, giving new features such as lightness with high efficiency. Besides that, it boosts the Portuguese economy as it is an underexplored market in Portugal.

Conclusions

Therefore, generally, the main points that characterize the NanoMask are:

- Particle filtration efficiency of about 99%;
- Weight reduction up to 30% compared to other types of thermoformed FFP2 masks present in the market;
- 45% of the mask structure is composed of biodegradable material;
- This biodegradable component can be reused and has a function in increasing comfort.

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Universidade do Minho

Tecminho

SCIENCENTRIS