

3-PLY MEDICAL FACE MASKS

TYPE IIR BFE \geq 98%



With your own logo and
coloured elastics



The IIR medical mask is a medical device designed to prevent the wearer from projecting droplets towards the wearer's entourage. It also protects the wearer of the mask from droplet projections emitted by crossed persons.

Product:

- ✓ Medical face mask
- ✓ 17.5 cm x 9.5 cm
- ✓ Medical device of class I in application of annex IX , European directive 93/42/CEE
- ✓ Type IIR according to EN14683 + AC 2019, CE certified

Description:

- ✓ 3-ply masks
- ✓ Professional
- ✓ Comfortable
- ✓ High elasticity ear loop
- ✓ High breathability

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Technical data sheet:

	Norm specification	Mask performance
Bacterial filtration efficiency	≥ 98%	≥ 99.5%
Respirability	< 60 Pa/cm ²	48 Pa/cm ²
Microbial cleanliness	< 30 CFU/g	< 30 CFU/g
Splash resistance	>16 kPa	>16 kPa

- Packaging:**
- ✓ Cardboard box of 50 masks
 - ✓ Plastic bag of 10 masks

Storage conditions:



Product validity: 2 years

Instruction for use:



1. Open the mask



2. Nose strip at the top, hung on the ear



3. Adjust the mask size to completely cover the nose and the mouth



4. Use both hands to regulate the binding bridge on the nose on both sides of the masks



5. Stamped side of mask to be placed outside

This product is a single-use product.

It is strictly forbidden to clean or reuse it.

Disposable face mask to be replaced every 4 hours.

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Déclaration CE de conformité - Dispositifs médicaux
EC Declaration of Conformity - Medical Devices

En vertu de la Directive 93/42/CEE du Conseil du 14 juin 1993 relative aux dispositifs médicaux
According to Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices

Fabricant légal	Nom <i>Name</i>	TEXTILCORD STEINFORT SA
	Adresse <i>Address</i>	Rue Schwarzenhof, BP 11 L-8401 Steinfort
Legal Manufacturer	Site Internet <i>Internet site</i>	www.glanzstoff.com
	Nom commercial / marque <i>Trade Name / Trade Mark</i>	TEXTILCORD STEINFORT SA
Produit Product	Nom / description <i>Name / description</i>	Masque Médical <i>Medical Mask</i>
	Nom commercial <i>Trade Name</i>	Non applicable
	Code Produit / Code Catalogue <i>Product Code / catalogue ref.</i>	PCM 0003+lettre
	Classification en vertu de l'Annexe IX de la Directive 93/42/CEE <i>Classification according to Annex IX of Directive 93/42/EEC</i>	Dispositif médical de Classe I (règle 1) <i>Class I Medical Device (Rule 1)</i>
	Norme applicable (Norme CE ou équivalente) <i>Applicable Specification</i>	EN 14683+AC :2019 Masques de type IIR <i>Type IIR Masks</i>

Nous, le fabricant légal, déclarons par la présente sous notre seule responsabilité que les produits susmentionnés sont conformes aux dispositions de la Directive 93/42/CEE du Conseil du 14 juin 1993 relative aux dispositifs médicaux. Le dossier technique de marquage CE est conservé dans les locaux du fabricant pendant toute la durée de vie du dispositif.

We, the legal manufacturer herewith declares under our sole responsibility that the above-mentioned products meet the requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. Technical file is retained under the premises of the manufacturer during the complete product life cycle.

Signature

VUARNESSON Céline, Managing Director

Nom du signataire et rôle
Name of authorised signatory and position

Lieu et Date 25 Mai 2021, Steinfort
Place, Date 25th of May 2021, Steinfort