

3-ply Surgical mask Type II TexiShield®

Medical Device Class I
EN 14683:2019 + AC:2019



*Respiratory protection in
infectious environments*

ADVANTAGES

- ✧ **Respiratory protection equipment** | Medical mask against solid and liquid particles
- ✧ **Comfort & fit** | Elastic ear straps
- ✧ **Light & soft** | Optimal material and design for continuous use up to 4 hours
- ✧ **Medical use** | EN 14683:2019+AC:2019 certified medical device - Type II not resistant to splashes
- ✧ **Available colors** | white, blue, green mask exterior
- ✧ **French manufacture** | Located in Auvergne-Rhône-Alpes region, France

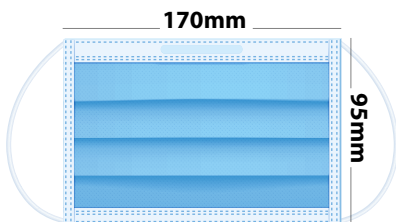
TECHNICAL DESCRIPTION

Brand : TexiShield® CH Type II
Use : Single use, non sterile
Colors : White, blue, green

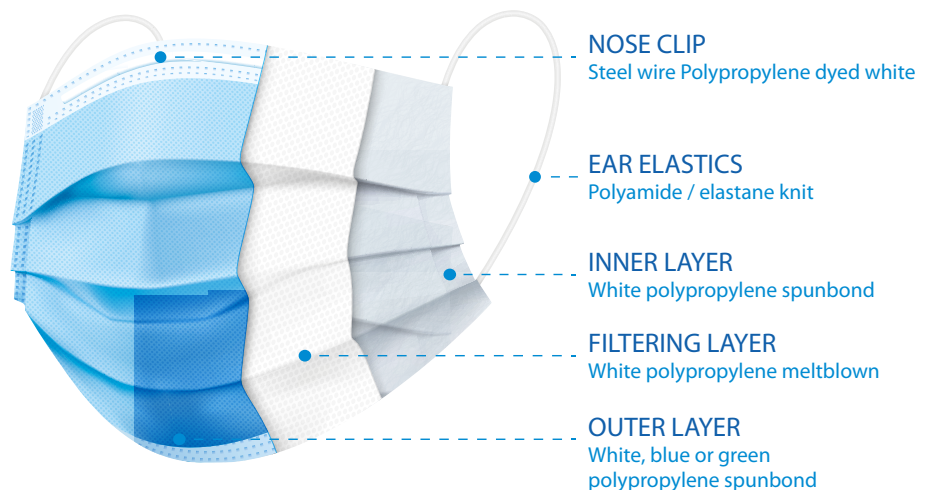
Expiry date : 5 years from manufacture date
Country of origin : France
Quantity : 50 masks in bags per box

References	Colors
TexiShield® CH-A02	
TexiShield® CH-B01	
TexiShield® CH-C01	

Dimension



GRAPHENE-FREE & LATEX-FREE 3-LAYER MASKS



CERTIFICATIONS

- ✧ Complies with the requirements of **the Medical Device (MD) Regulation (EU) 2017/745** and the applicable **standard EN 14683:2019 + AC:2019**
- ✧ Manufacturing units under **ISO 9001:2015** and **ISO 13485:2016** certified quality management systems (QMS)

STANDARD REQUIREMENTS

EN 14683:2019+AC:2019

Test	Standard	Requirement	Results
Bacterial Filtration Efficiency (BFE)	EN 14683:2019+AC:2019	≥ 98 % (Type II)	✓ Compliant
Breathability (Differential pressure)	EN 14683:2019+AC:2019	< 40 Pa/cm ²	✓ Compliant
Microbial cleanliness	EN 14683:2019+AC:2019	≤ 30 ufc/g	✓ Compliant
Cytotoxicity	ISO 10993-5	No cytotoxicity	✓ Compliant
Irritation / Sensitization *	ISO 10993-10	Non-irritant / non-sensitising	✓ Compliant

* Microbiological test on request

PACKAGING

References	Colors	EAN code	Packaging Case 30 x 38 x 28 cm	Weight	Pallet size (cm)
TexiShield® CH-A02		3770021816504	12 boxes of 50 masks per case	Mask : 2,95 g Box of 50 : 203,82g Case : 2,6 kg	L80 x P120 x H210
TexiShield® CH-B01		3770021816511			
TexiShield® CH-C01		3770021816528			

Note: Special packaging on request

STORAGE & PRECAUTIONS

- Store according to the recommendations on the packaging (**between 5 and 40°C and below 70% humidity**).
- The product expires **5 years after the date of manufacture**.
- Follow the instructions for use.**
- Recommended continuous wearing time: max. 4 hours

PACKAGING MARKING

Legal manufacturer

Batch number

Reference

Expiry date

Store away from direct sunlight

Store away from moisture

Storage or preservation temperature

Non-sterile device

Latex-free product

Single use

Medical Device

Leaflet and box to be sorted for recycling

Recycling box

Consult recommendations

