

3-ply Surgical mask

Type II R

TexiShield®

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



*Respiratory protection in
infectious and hospital
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 R splash resistant
- ✧ **Available colors** | white, blue, green mask exterior
- ✧ **French manufacture** | Located in Auvergne-Rhône-Alpes region, France

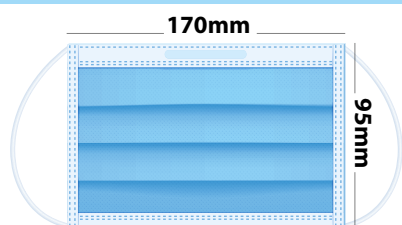
TECHNICAL DESCRIPTION

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

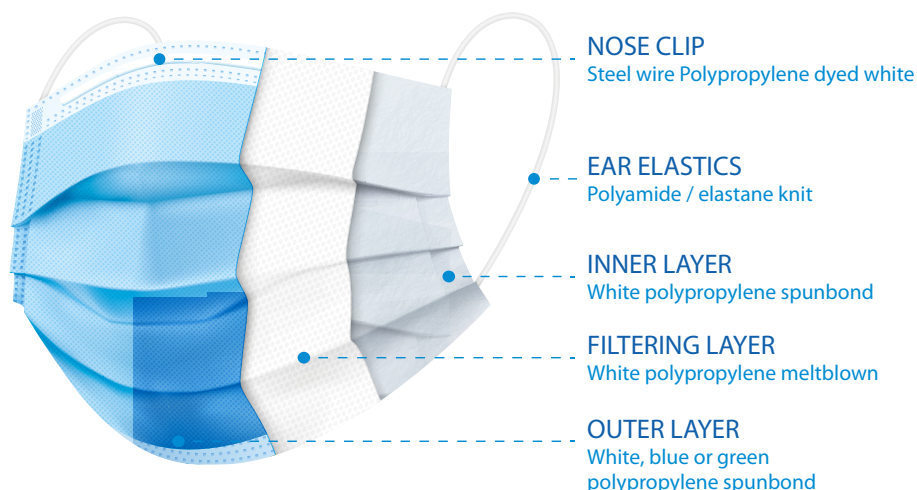
Expiry date : 5 years from manufacture date
Country of origin : France
Quantity : 50 masks in bags per box

References	Colors
TexiShield® CH-A03	
TexiShield® CH-B02	
TexiShield® CH-C02	

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 R)	✓ Compliant
Breathability (Differential pressure)	EN 14683:2019+AC:2019	< 60 Pa/cm ²	✓ Compliant
Splash resistance	EN 22609:2004	≥ 16 kPa	✓ 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-A03		3770021816535	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-B02		3770021816542			
TexiShield® CH-C02		3770021816559			

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

