klap

3-ply Mask for medical use, BLUE Medical imaging compatible CE-Marking (Type IIR) - ENI4683 Made in France

V II.04.2022



Category	Non-sterile Class I Medical device Single-use surgical mask (type IIR)				
Standard and legislation	 EU Medical Devices Directive 93/42/EEC Complies with standard EN 14683:2019+AC:2019 				
Description	 Mask for medical use, non-sterile, for single use, Model : 1000 series Specifications : WITHOUT NOSE BAR: compatible with medical imaging Size M Dimensions: M. 170 x 95 mm Bacterial filtration efficiency: see performance table Mask weight (+/- 5%): Type IIR : M 2.90 gr 				
Composition	 Inner and outer layers: polypropylene nonwovens spunbond . Intermediate layer: nonwovens meltblown in polypropylene. Elastic: Polyamide / spandex mesh ou polypropylene / spandex mesh French manufacturing lines - Controlled raw materials and products 				
Materiovigilance	The materials likely to come into contact with the wearer's skin do not present a risk of irritation or harmful effects to health.				
Storage and preservation	Mask should be stored in a clean, dry, cool and well-ventilated place. Humidity less than 80%, temperatures between +5°C and +40°C. Maximum storage period: 5 years in their original packaging.				

KLAP France SAS

3-ply Mask for medical use, BLUE Medical imaging compatible CE-Marking (Type IIR) - ENI4683 Made in France

klap

V II.04.2022

Performances	EN 14683:2019 Type Type II-R	Bacterial filtration effectiveness (BFE) ≥ 98 %	Differential Pres- sure (Pa/cm²) < 60	Resistance to projections (kPa) ≥ 16	Cleanliness microbial (cfu/g) ≤ 30	
Duration of use	4 hours maximum (in one shift – continuous)					
Sector of use	 General public Professional, sectors for example : Medical sector not exposed to projections and splashes Medical sector exposed to projections and splashes Service, community, visitors Infrastructure, construction Light industry Logistics transport Medico-Social Retirement home Schools Various exposed areas protecting the wearer against the health risk 					
Packaging	Box of 50 units 30 boxes in one cardbo Packaged without bags Or 5 bags of 10 masks	ard	MADEIN	FRANCE	Managa Anaraman Managa Anarama	



KLAP France SAS