Medical Face Mask Type IIR - EN 14683



The table below indicates the performance requirements defined by EN 14683-2019. This product meets European Standard EN 14683 for medical face masks Type IIR. The product is also covered by Declaration of Conformity with European Directive, Document No. KB/CE-011-03. In addition, the manufacturer's Quality Management System is certified for compliance with EN IS013485:2016 by TÜV SÜD Product Service GmbH, Germany, Certificate No. Q6 050970 0016 Rev. 01.

Conformity with European Norms, Medical Device Directives and International Standards ISO

Test	Туре / Тур I *	Type / Typ ll	Type /Typ IIR
Bacterial filtration efficiency (BFE) (%)	≥ 95 %*	≥ 98 %	≥ 98%
Differential pressure (Pa/cm ²)	<40*	<40	<60
Splash resistance pressure (kPa)	Not required*	Not required*	≥16,0
Microbial cleanliness (cfu/g)	≤ 30[*]	≤30	≤30

*Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.





Distributed in the US by: MediVena

1 Glenlake Parkway, Ste 700 Atlanta, GA 30328, USA

- **L** +1 404 514 2586
- info@medivena.com

Distributed in European Union by: Medivena Sp. z o.o.

 Aleja Jana Pawła II 27 00-867 Warszawa, POLAND

↓ +48 661 920 142
∰ info@medivena.com

