

SUSPIRE swiss



EU DECLARATION OF CONFORMITY

We,

SUSPIRESWISS SA, 29 Chemin de Grange-Canal, 1223 Cologny (Switzerland)

declare under our sole responsibility, that the product below:

Description of the Product: **3 plies Foldable Surgical Mask/Half Face/Non-Reusable/Type IIR (Blue)**

Brand Name: **SUSPIRE** Model Names: **SS-FSM02R**

meets the following European regulation: **EN 14683:2019**

Applicable standards:



Code	Standard	Description
MK-02	UNI EN 14683.2019 par 5.2.3. + Annex C	Face masks for medical use - Requirements and test methods - Breathability Differential pressure
MK-04 (s)	UNI EN 14683:2019 par 5.2.5 + Annex D	Medical face masks - Requirements and test methods - Method for determination of microbial cleansing
MK-05 (s)	UNI EN 14683:2019 par 5.2.2 + Annex B	Medical face masks - Requirements and test methods - Method for determination of bacterial filtration efficiency (BFE)
MK-06	SO 22609:2004 + UNI EN 14683.2019 par 5.2.4.	Clothing for protection against infectious agents - Medical face mask - Test method for resistance to penetration of synthetic blood
MK-03(*) (s)	UNI EN 10993-1:2010	Biocompatibility and cytotoxicity, verified by in vitro tests using human dermis cells according to UNI EN 10993-5:2009, including rational for the verification of biocompatibility.

Relevant Tests had been performed by the Accredited Laboratory:



Qualità e Logistica Srl
Via Repubblica 3
22075 Lurate Caccivio (CO)

Signed for and on behalf of SUSPIRESWISS SA
Gèneve, 30 November 2020

Johnny Nicastro

COO and Member of the Board of Directors