



## CE DECLARATION OF CONFORMITY

**Manufacturer:** Miroglio Textile S.r.l.  
**Registered Address:** Strada Santa Margherita n.23  
12051 Alba (CN)  
**Production unit:** Viale G.Nogaris n.20, Frazione Pollenzo,  
12042 Bra (CN)

**Person authorized to compile  
the technical construction file:  
Registered Address:** Miroglio Textile S.r.l.  
Strada Santa Margherita n.23  
12051 Alba (CN)  
**Production unit:** Viale G.Nogaris n.20, Frazione Pollenzo,  
12042 Bra (CN)

***It is hereby declared that the following medical device:***

**Model:** **S777E**  
**Type:** **Type II - single-use non-sterile 80 g/sqm SMS surgical face mask**

meets the applicable essential requirements of Medical Device Directive 93/42/EEC, incorporated into Italian law with Legislative Decree n. 46 of February 24<sup>th</sup> 1997, and therefore bears the CE mark.

Relevant harmonized standards:

**UNI EN 14683:2019** - "Medical face masks – Requirements and test methods"

**UNI EN ISO 10993-1:2010** - "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system"

**UNI CEI EN ISO 14971:2012:** - "Application of risk management to medical devices"

**UNI CEI EN 1041:2013** - "Information supplied by the manufacturer of medical devices"

**UNI CEI EN ISO 15223-1:2012** - "Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements"

On the basis of section III of Annex XI of Directive 93/42/EEC, the above-mentioned medical device is classified as:

**Class I non-sterile and without a measuring function.**

This declaration of conformity only applies to the devices described herein and used in compliance with the related instructions for use.

Alba, 15/07/2020

Stamp and signature