

# Declaration of Conformity to Council Directive EC/93/42

**Apparel MED**



This declaration of conformity is made by Diarmuid Cahalane of Apparel Supply Limited which has its place of business at Worklab, IDA Industrial Estate Waterford X91 DC96, Ireland. Apparel Supply Limited conforms with the provisions of Medical Device Directive EC/93/42.

This declaration of conformity is issued under the sole responsibility of Apparel Supply Limited as the manufacturer.

This document is the declaration from Apparel Supply Limited to indicate that the organisation conforms to all appropriate directives, regulations, and guidelines according to the Medical Device Directive.

## Scope

This declaration applies to the Apparel Med Medical Facemask:

Apparel Supply Limited declare that the Apparel Med Medical Face Mask meets the transposition into national law, of the provisions of council directive EC/93/42 and EN 14683:2019 and AC:2019 Type 11R. (Surgical Face Mask)

The harmonized standard for which documented evidence of compliance can be provided is ISO 13485:2016.

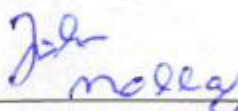
## Responsibilities

Apparel Supply Limited senior management, CEO, General Manager, and Person Responsible for Regulatory Compliance are responsible for this Declaration of Conformity and shall ensure that the Quality Policy is appropriate to the purpose of the organisation and is understood, implemented, and maintained at all levels of the organisation.

Signed on 29<sup>th</sup> March 2021:

Signed: 

Diarmuid Cahalane  
(Person  
Responsible for  
Regulatory  
Compliance.

Signed: - 

John Molloy  
Managing Director

Signed: - 

Corinna Dower,  
General Manager