

	<p><b>DECLARATION OF CONFORMITY CE</b></p>	<p style="text-align: center;">TF01 - Allegato V Rev. 00 - June 2020</p> <hr/> <p style="text-align: center;">Page 1 out of 1</p>
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## DECLARATION OF CONFORMITY

Within the meaning of directive 93/42/EEC and subsequent amendments and modifications, the writing company: **CIFRA SPA** registered offices in Verano Brianza- Via Sabbionette 7 – 20843 (MB)

In charge of Manufacturer of the medical device:

### “WARPMASK”

Cod. C2 090MF 11683 RD MK 07M  
 Cod. CJ 090MF 11677 RE MK SM  
 Cod. CJ 90VRE 11677 RG MK SM  
 Cod. CJ N90MF 11677 RC MK SM  
 Cod. CJ 090MF 11736 RB MK SM

Declares under its **own responsibility** that the MD complies to the essential requirements and dispositions of Directive 93/42/ECC, according to the technical file available at Italian World’s headquarters:

The writing company declares that:

- the above-mentioned device is considered pertaining to Class I in accordance with Annex IX, Chapter III (classification); 1.1 (rule 1), according to Directive 93/42/EEC and subsequent amendments and modifications;
- the above-mentioned device complies with essential requirements of Annex I in Directive 93/42/EEC and subsequent amendments and modifications;
- the above-mentioned device is produced according to Quality System that complies to the requirements listed in Annex V of the Directive 93/42/EEC.

The manufacturer has duty to maintain this declaration of conformity and the technical documentation (described in Annex VII of the Directive 93/42/EEC) available for any Competent Authority request in the **CIFRA SPA** site located in Verano Brianza, via Sabbionette 7, 20843 (MB) – Italy for a period of **10 years** from the last manufacturing date.

We hereby declare that the above-mentioned medical device complies with the requirements of Directive 93/42/EEC and subsequent amendments and updates, so it will be marketed with the CE label in accordance with Article 17 and Annex VII of Directive 93/42/EEC.

Place: Verano Brianza

Date: 10/06/2020

On behalf of the Legal Representative Cesare Citterio

