



# Declaration of conformity

I, the undersigned, Giuseppe Santarcangelo, as Legal Representative of the Company

**AF STUDIO SRL – AF PHARMA Division**

Via Giorgio Sidney Sonnino, 4 – 43126 Parma (PR)

VAT No.: 02467870347

Declare under sole responsibility that the device:

**Disposable Surgical Mask**

**Model AF03-GO**

Is classified according to Annex VIII of Regulation (EU) 2017/745 as

**disposable Class I Medical Device**

Is in conformity with the following norms:

- ISO 14971:2012: Medical devices. Application of risk management to medical devices;
- ISO 1041:2009: Information supplied by the manufacturer of medical devices;
- ISO 15233-1:2017: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements;
- ISO 9001:2015: Quality management systems — Requirements;
- Regulation (EU) No 1007/2011: Regulation on textile fibre names and related labelling and marking of the fibre composition of textile products;
- ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;
- ISO 14683:2019: Surgical masks: Requirements and test methods

And meets the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745.

The Technical documentation is available at the following address:

Via Giorgio Sidney Sonnino, 4 – 43126 Parma (PR)

Parma (PR), 17.02.2021

Firma: