



## Declaration of Conformity

We the manufacturer:

**ARISTE S.R.L.**  
**Via Leonardo Da Vinci 5**  
**Po. Box 24053 Brignano Gera D'Adda**  
**Bergamo - Italy**

We declare that the below mentioned product satisfies the requirements laid down in General Safety and Performance Requirements of Medical Device Regulation (EU) 2017/745.

Product classification:  
class I (RULE 1)

purpose:  
Filtration of sprouts and protection against splashes during a surgery

**PREMIUM MASK | Type IIR**

ARISTE

### Harmonized Standards:

EN ISO 14971:2012 ,EN ISO 15223-1:2016,EN 1041:2008, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 14683:2019+AC:2019

Edoardo Buttinoni  
General Manager

07.07.2021

Date