

Legal Manufacturer:	PROMEIA S.p.A.		
Legal offices:	I-20141 - Milan - Via Cardinale Ascanio Sforza 85 - Italy		
Plant address:	I-21042 - Caronno Pertusella (VA) - Corso della Vittoria 1585/1533 - Italy		
Class:	1	Technical File Nr.:	FT 002 PR current edition
Art. Nr.	610000000001		

Commercial Name:	Surgical Masks	Customer:	Aigoo srl
Market:	ITALY		
Intended Use:	Disposable surgical masks for medical use		

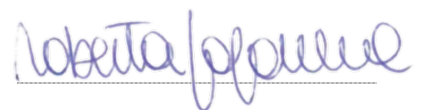
Batch Nr.:	0020201	Expiry date:	2022/11
Release date:	21/12/2020	Quantity released:	1000 pcs

PROMEIA S.p.A. declares, on his own responsibility, that the medical devices denominated "surgical masks" in compliance with rule 1 of Annex IX of Directive 93/42/EEC and any subsequent amendments and additions (implemented in Italy with Legislative Decree of 24 February 1997, n. 46, and any subsequent amendments and additions), as modified by Directive 2007/47/EC (implemented in Italy by Legislative Decree 25 January 2010, n. 37),

- satisfy the essential requirements and the provisions of the Directive 93/42 / EEC and any subsequent amendments and additions as Technical File n. FT 002 PR above mentioned achieved c/o the company;
- has been manufactured in accordance with the Quality System that satisfies the requirements of Annex VII of the aforementioned Legislative Decree no. 46 of 24/02/97 and subsequent amendments
- comply with the UNI EN 14683: 2019 - type II standard

Date of declaration: 21/12/2020

Signature QA Manager:



Signature CEO:

