	DECLARATION OF CONFORMITY CE **NINOMASK** **(Class I)** Council Directive 93/42/EEC	TF01 Rev.00 19.01.2021

DECLARATION OF CONFORMITY

CE

Declaration of conformity according to Annex VII of Council Directive 93/42/EEC (implemented with Legislative Decree No. 46 of 24/02/1997) as modified by Directive 2007/47/EC (implemented with Legislative Decree No. 37 of 25/01/2010) of the class I medical device (rule 1), called

NINOMASK

IDENTIFICATION DATA			
Manufactured		**Registered office address**	
IDEA SRLS		Via Orosei, 64	
Postal Code	**Location**	**Province**	**State**
56021	Cascina	PI	Italia
Commercial Name		**Typology**	
NINOMASK		Mask	
Intended Use		**Risk class**	**Classification Rule**
The NINOMASK medical face mask is a medical device that covers the mouth, nose and chin of the user, providing a barrier that limits the direct transmission of infectious agents.		I	1
Product Code		**Reference to the production lot**	
NINOMASK 3.0120		120/22874/01/03/02	

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IDEA Srls, as the manufacturer of the medical device:

NINOMASK

Declare

under its own responsibility that the device in question meets all the applicable provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EEC and complies with the following regulatory standards:

• UNI EN 14683:2019 “Face masks for medical use - Requirements and test methods”;

• UNI CEI EN ISO 14971:2020 “Medical devices - Application of risk management to medical devices”;

• ISO / TR 24971:2020 "Medical devices - Guidance on the application of ISO 14971";

• UNI CEI EN ISO 15223-1:2017 "Medical devices - Symbols to be used in the labels of the medical device, in the labeling and in the information to be provided - Part 1: General requirements";

• UNI CEI EN 1041:2013 “Information provided by the manufacturer of medical devices”;

• EN ISO 10993 series “Biological evaluation of medical devices”.

Furthermore, the sole administrator declares and guarantees that:

• The device is to be considered as belonging to class I;

• The device does NOT incorporate human blood derivatives or substances that can be considered medicinal specialties referred to in point 7.4 of Annex I;

• The device does NOT contain tissues or substances of animal origin;

• The device is not a measuring instrument and is not intended for clinical investigations.

Place and date Cascina, 19/01/2021

Signature Roberto Trabeati