

# CE DECLARATION OF CONFORMITY CE

## According to Annex VII of Directive 93/42/CEE on Medical Devices

Doc. ID: MED-IIR Rev0

<i>Manufacturer:</i>	BROMAS LOG SRL
<i>Address:</i>	Via Donatello, 19/C 59016 Poggio a Caiano (PO) Italy
<i>Email:</i>	bromaslogsrl@pec.it
<i>Telephone No.:</i>	+39 055 0197548
<i>Product code:</i>	MED IIR
<i>Registration Code (BD/RDM in Italy):</i>	2060923
<i>Intended purpose:</i>	As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. Moreover, it is designed to be fluid resistant to splash and spatter of blood and other infectious materials. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.
<i>Classification:</i>	Non-sterile Class I medical device without measuring function (Annex VII of Directive 93/42 EEC concerning medical devices)
<i>Reusability:</i>	Single-use device
<i>Harmonized Standard which Comply with:</i>	EN 14683 :2019 + AC:2019 Medical Face Masks. Requirements and Test Methods. EN ISO 10993-1:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
<i>Conformity assessment procedure:</i>	The device has been subjected to a series of tests and evaluations according to the aforementioned standards. The test results, documented in the test reports attached to the Technical File uploaded on the portal of the Italian Ministry of Health, demonstrate the compliance of the device with the aforementioned standard for the device type and reuse (if any) possibilities declared in the attached instructions.
<i>Start of CE marking:</i>	23/02/2021
<i>Expire date of the Declaration:</i>	22/02/2026
We, the manufacturer, herewith declare under our sole responsibility that the above mentioned devices meet the provisions of the Directive 93/42 EEC concerning Medical Devices (MDD). All supporting documentation is retained under the premises of the manufacturer.	

*Place:* 59016 - Poggio a Caiano - Italy

*Date:* 23/02/2021

*Name and Family Name:* Anna Pelucchi

*Role:* Legal representative

*Signature:*

