



EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

EN

Manufacturer:	FIAB SpA
Registered address:	Via Costoli 4, 50039 Vicchio (FI), Italia
Single Registration Number:	IT-MF-000005988
Basic UDI-DI:	803300326101000005K9
Product name/ Intended Purpose	Oxygenotherapy mask with variable concentration
Models:	See list in Attachment
Technical Documentation File	TDF 101
Risk Class (MDR Annex VIII):	IIA
Conformity assessment procedure performed:	Annex IX – Conformity assessment based on a quality management system (Chapter I)
Notified Body	BSI Group The Netherlands B.V. 2797
Certificate(s) issued	EU quality management system certificate MDR 747884 R000
Technical standards and/or Common Specifications applied:	EN 62366 [2015] - EN ISO 10993-1 [2020] - EN ISO 13485 [2016] - EN ISO 13544-1 [2007+A1:2009] - EN ISO 13544-2 [2002+A1:2009] - EN ISO 13544-3 [2001+A1:2009] - EN ISO 14971 [2019] - EN ISO 15223-1 [2021] - EN ISO 20417 [2021]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we hereby declare

- that the medical devices specified meet the provision of the Regulation (EU) 2017/745 for medical devices
- that the procedures of FIAB quality management system according to ISO 13485 have been followed, Certificate of Registration no.MD77846 issued by BSI
- that the products do not contain medicinal substances, elements of animal origin or their derivatives, human blood derivatives, and are latex free

Signature:

Vicchio, 03/02/2023

Alberto Calabrò
Managing Director

Declaration Code EU-00000074-101

First issued: 03/02/2023

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Cod 99500201MD4A

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Attachment of EU Declaration of Conformity – List of models

OS/60K - OS/60KD - OS/62K - OS/70K - OS/70KD - OS/72K - OS6K
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