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:	803300326101000006KB
Product name/ Intended Purpose	High concentration oxygentherapy mask
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 herby 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-00000075-101	First issued:	03/02/2023
		Last revised:	03/02/2023

Cod 99500201MD4A

FIAB SpA – 50039 Vicchio - Firenze - Italia
Sede legale: Via P. Costoli, 4 - Logistica: Via Meglini, 2-4
Unità operative: Via Passerini, 2-3-4-6 – Via della Resistenza, 18
Tel. +39 0558497999 - Fax +39 0558497979 - www.fiab.it
Cap. Soc. int. vers. 2.000.000,00 € - C.F.P.I. e n. Reg. Imp. FI 01835220482 - Trib. FI. n.3354 I
C.C.I.A.A. FI n. 339066 REA - c/c postale 14476501 - EUROPEAN VAT: IT 01835220482

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

EN

Attachment of EU Declaration of Conformity – List of models

OS/50 - OS/50D - OS/50E - OS/50P - OS/50PD

Declaration Code	EU-00000075-101	First issued:	03/02/2023
		Last revised:	03/02/2023

Cod 99500201MD4A

FIAB SpA – 50039 Vicchio - Firenze - Italia
Sede legale: Via P. Costoli, 4 - Logistica: Via Meglini, 2-4
Unità operative: Via Passerini, 2-3-4-6 – Via della Resistenza, 18
Tel. +39 0558497999 - Fax +39 0558497979 - www.fiab.it
Cap. Soc. int. vers. 2.000.000,00 € - C.F.-P.I. e n. Reg. Imp. FI 01835220482 - Trib. FI. n.3354 I
C.C.I.A.A. FI n. 339066 REA - c/c postale 14476501 - EUROPEAN VAT: IT 01835220482