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

EN

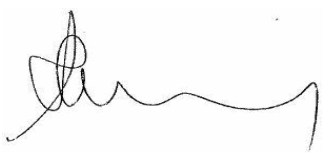
Manufacturer:	FIAB SpA
Registered address:	Via Costoli 4, 50039 Vicchio (FI), Italia
Single Registration Number:	IT - MF - 000005988
Basic UDI-DI:	803300326001000003JE
Product name:	Extension for oxygen
Intended Purpose:	Therapeutic administration of oxygen
Models:	See list in Attachment
Technical Documentation File:	TDF 001
Risk Class (MDR Annex VIII):	IIA
Conformity assessment procedure performed:	Annex IX - Chapter I and Chapter III
Notified Body:	BSI Group The Netherlands B.V. 2797
Certificate(s) issued:	EU quality management system certificate: MDR 747884 R00
Technical standards and/or Common Specifications applied:	EN ISO 10993-1 [2020], EN ISO 13485 [2016], EN 13544-2 [2002+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
- are latex free

Signature

Alberto Calabrò
Managing Director



Vicchio, 25/09/2024

Declaration Code	EU-001000003-001-2	First issued:	31/01/2023
Cod 99500201MD4B		Last revised:	25/09/2024

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Attachment of EU Declaration of Conformity - List of models

OS/40, OS/400, OS/40-20, OS/41, OS/410

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Cod 99500201MD4B		Last revised:	25/09/2024

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