

EU Declaration of Conformity

Document Number:	DC-AMS-01	Revision:	02
Technical File Number:	TF-AMS-01 fabian HFO and HFO light ventilators		

Legal Manufacturer	Acutronic Medical Systems AG - Fabrik im Schiffli, 8816 Hirzel, Switzerland
Product	fabian™ HFO and HFO light
Product Codes	See Attachment
GMDN Codes	See attachment
Authorized Representative	Emergo Europe - Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
We, the manufacturer hereby declare under sole responsibility that the products listed in this document are in conformity with the Essential Requirements of Annex I and meets the provisions of Council Directive 93/42/EEC, as amended by 2007/47/EC for medical devices, and Regulation (EU) 2017/745 for medical devices (Article 120 Transitional Provisions – paragraph 3 and 4). The medical devices are manufactured under control of ISO 13485:2016 Quality Management System.	
General applicable Directives and Regulations:	Medical Device Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices Regulation (EU) 2017/745 of 5 April 2017 for medical devices (Article 120 Transitional Provisions – paragraph 3 and 4)
Notified Body	TÜV NORD CERT GmbH - Am TÜV 1, 45307 Essen, Germany: CE 0044
EC Certificate(s)	Reg. No. 44 232 141950 (valid until 31-Dec-2028) see Extension Letter
Annex	MDD 93/42/EEC Annex II, excluding section (4)
Quality System Certificate	TUV NORD 44 221 141950, Expires 08 Feb 2024
Full Quality System	ISO 13485:2016
Other applicable Directive	ROHS Directive 2011/65/EU of 8 June 2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment

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0312-001-009-R Rev. 11
Effective: 11JUL2023
CRF#: 2023-080

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*Electronically signed by: Terrie
McDaniel
Reason: I approve this document
Date: Mar 13, 2024 12:37 CDT*

VP, Global Quality Assurance and Regulatory Affairs
Terrie McDaniel

Date and Place
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Agboli
Reason: I approve this document
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Legal Manufacturer Representative
Abraham Agboli, Sr. Manager QA

Date and Place
Fabrik im Schiffli, 8816 Hirzel, Switzerland


*Electronically signed by: Abraham
Agboli
Reason: I approve this document
Date: Mar 13, 2024 19:01 GMT+1*

PRRC Designee
Abraham Agboli, Sr. Manager QA

Date and Place
Fabrik im Schiffli, 8816 Hirzel, Switzerland

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Attachment: Product Device Listing

Product Code	Product Description	EU Class	Rule(s)	GMDN Code
113001	fabian HFO	IIb	11	14361
111001.01	fabian HFO light	IIb	11	14361

GMDN Code	GMDN Term
14361	Ventilators, Intensive Care, Neonatal/Pediatric

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0312-001-009-R Rev. 11
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Revision History (Internal use only)

Revision	Date	Author	Change Description
01	18 July 2023	Sindhu Sridhar	DRAFT – Initial Issue
02	07 Mar 2024	Pauline Lieu	Physical Manufacturer Update

Revision History for document

Revision	Change Summary	Change Control #
10	Added AG after Acutronic Medical Systems, removed 2 redundant columns on device listing, added Emergo's new address, transfer to new Vyaire template	2023-007
11	Remove old address of the EU Authorized Rep from the drop-down list. Replace old address of TUV Nord with new address in the drop-down list	2023-080
ADMIN	ADMIN update to correct header format	N/A

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Final Audit Report

2024-03-13

Created:	2024-03-13
By:	Elizabeth Lipp-Rawski (Elizabeth.Lipp-Rawsk@vyaire.com)
Status:	Signed
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"TF-AMS-01-02 -fabian HFO & HFO Light EU Declaration of Co nformity" History

-  Document created by Elizabeth Lipp-Rawski (Elizabeth.Lipp-Rawsk@vyaire.com)
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-  Email viewed by Terrie McDaniel (Terrie.McDaniel@vyaire.com)
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-  Document shared with Pauline Lieu (Pauline.Lieu@vyaire.com) by Elizabeth Lipp-Rawski (Elizabeth.Lipp-Rawsk@vyaire.com)
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