

EU Declaration of Conformity

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

Document Number:	DC031	Revision:	02
Technical File Number:	90-R0222 Rev. 07		

Legal Manufacturer	Vyaire Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	Infant Flow LP Class II
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	BSI Group The Netherlands B.V. - Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands: EC 2797
EC Certificate(s)	CE 703694 (valid until 31 December 2028)
Annex	Annex II, excluding section 4
Quality System Certificate	FM 555335 (valid until 02-Jan-2027) MDSAP 681543 (valid until 02-Jan-2027)
Full Quality System	ISO 13485:2016



Electronically signed by: Sindhu Sridhar
Reason: I approve this document
Date: May 23, 2024 16:34 PDT

23-May-2024 Irvine, CA

Regulatory Affairs VP/Director/Manager or Designee
Sindhu Sridhar, Sr. Manager, Regulatory Affairs

Date and Place



Electronically signed by: Steven Berryhill
Reason: I approve this document
Date: May 23, 2024 14:58 PDT

23-May-2024 , Palm Springs, CA

QA Manufacturing Site Representative or OEM Quality Designee
Mark Berryhill, Sr. Director, Quality Operations

Date and Place



Electronically signed by: Sindhu Sridhar
Reason: I approve this document
Date: May 23, 2024 16:34 PDT

23-May-2024 Irvine, CA

PRRC Designee
Sindhu Sridhar, Sr. Manager, Regulatory Affairs

Date and Place

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Attachment: Product Device Listing

Product Code	Product Description	EU Class	Rule(s)	GMDN Code
7772021	PCKG ASSY GNRTR KIT W RT132 CIRCTS	Class IIa	Rule 11	37498
7772011	PACKAGE ASSEMBLY,GENERATOR KIT W/RT132 CIRCUITS	Class IIa	Rule 11	37498
7772020LP	PACKAGE ASSEMBLY, INFANT FLOW, LP	Class IIa	Rule 11	37498
7772000LP	PACKAGE ASSEMBLY, GENERATOR WITHOUT PRONGS	Class IIa	Rule 11	37498
777000XS	INFANT FLOW LP NASAL PRONGS,EXTRA SMALL	Class IIa	Rule 5	35202
777000S	INFANT FLOW LP NASAL PRONGS,SMALL	Class IIa	Rule 5	35202
777000M	INFANT FLOW LP NASAL PRONGS,MEDIUM	Class IIa	Rule 5	35202
777000L	INFANT FLOW LP NASAL PRONGS,LARGE	Class IIa	Rule 5	35202
777000XL	INFANT FLOW LP NASAL PRONGS,EXTRA LRGE	Class IIa	Rule 5	35202
777002XS	INFANT FLOW LP NASAL MASKS,EXTRA SMALL	Class IIa	Rule 2	37591
777002S	INFANT FLOW LP NASAL MASKS,SMALL	Class IIa	Rule 2	37591
777002M	INFANT FLOW LP NASAL MASKS,MEDIUM	Class IIa	Rule 2	37591
777002L	INFANT FLOW LP NASAL MASKS,LARGE	Class IIa	Rule 2	37591
777002XL	INFANT FLOW LP NASAL MASKS,EXTRA LRGE	Class IIa	Rule 2	37591

GMDN Code	GMDN Term
37498	Respiratory Oxygen Therapy System
35202	CPAP Nasal Oxygen Cannula
37591	CPAP/BPAP Nasal Mask, Single-Use

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Revision History (Internal use only)

Revision	Date	Author	Change Description
00	4 Feb 2019	Nadia Ahmed	New DoC. Class II P/Ns transferred from 90-R0226, 90-R0298, 90-R0299, and 90-R0227 to DC031 due to rebranding. Removed product code 7772010. Removed GMDN 61833, 37706, and 60966 and replaced it with 37498. Updated legal manufacturer from CareFusion Yorba Linda to Vyairé Medical Mettawa. Updated CE marking from CE 0086 to CE 2797 due to change in Notified Body number. Updated Notified Body from BSI Product Services UK to BSI Group The Netherlands.
	4 Feb 2019	Anna McManus	Added "Infant Flow SIPAP Localization Kits" and 467349 (Abdominal respiratory sensor) from Class I DoC as these are classified as Class IIa. Removed 11513-101, 11513-102, and 11513-103 as they aren't in rebranding scope. Removed 'Kit Components' section as does not pertain to this document. Updated to new Vyairé Template Amended CE Certificate Number from CE00663 to CE703691
01	06 Oct 2020	Karen Mudd	Remove SKUs 777086-101, 777086-102, 777086-103, 777086-104, 777215, D1420/100, 777085-102, 12204-101, 77389-104, 12204-102, 11541-102 and not in scope for rebranding. Removed GMDN codes 61346, 60837, 32202 as not in scope for rebranding. Removed 25655-001, 25656-001, 25657-001, 25659-001, 25672-001 as not in scope for rebranding. Removed 467349. This is a class I device per Rule 1 and has been moved to DC030. Update EC certificate number from CE703691 to CE703694
02	24-May-2024	Paola Lerma	Updated template Removed product codes not moving to MDR and that have lost CE mark as of 26 May 2024: 26404-001, 26405-001, 27031-001

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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

Signature: 

Electronically signed by: Melissa Souder
Reason: I approve this document
Date: May 24, 2024 09:04 PDT

Email: melissa.souder@vyaire.com









1.1_ 2024.05.22 DC031 Infant Flow LP Class II EU DOC Rev. 02_Final

Final Audit Report

2024-05-24

Created:	2024-05-23
By:	Melissa Souder (melissa.souder@vyaire.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAbKQAIYuKWH5Owq81T0GRt0969uuJWP_Q

"1.1_ 2024.05.22 DC031 Infant Flow LP Class II EU DOC Rev. 02_Final" History

-  Document created by Melissa Souder (melissa.souder@vyaire.com)
2024-05-23 - 5:27:47 PM GMT
-  Document emailed to Steven Berryhill (mark.berryhill@vyaire.com) for signature
2024-05-23 - 5:28:51 PM GMT
-  Document emailed to Sindhu Sridhar (SINDHU.SRIDHAR@vyaire.com) for signature
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2024-05-23 - 9:58:53 PM GMT
-  Document e-signed by Steven Berryhill (mark.berryhill@vyaire.com)
Signing reason: I approve this document
Signature Date: 2024-05-23 - 9:58:55 PM GMT - Time Source: server
-  Email viewed by Sindhu Sridhar (SINDHU.SRIDHAR@vyaire.com)
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Signing Reasons

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Signature Date: 2024-05-23 - 11:34:34 PM GMT - Time Source: server

- ✓ Melissa Souder (melissa.souder@vyaire.com) authenticated with Adobe Acrobat Sign.

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- ✓ Melissa Souder (melissa.souder@vyaire.com) authenticated with Adobe Acrobat Sign.

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