

Declaration of Conformity

Legal Manufacturer	Vyairé Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	Infant Flow SiPAP Accessories Class II
Product Codes	See Attachment
GMDN Codes	See attachment
EC Representative	Emergo Europe - Prinsessegracht 20, 2514 AP The Hague, 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. The medical devices are manufactured under control of ISO 13485:2016 Quality Management System.	
General applicable directives:	Medical Device Directive: Council Directive 93/42/EEC of 14 June, 1993 as amended, concerning medical devices
Notified Body	BSI Group The Netherlands B.V. - Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands
EC Certificate(s)	CE703694
Annex	II, excluding section 4
Quality System Certificate	FM 555355 MDSAP 681543
Full Quality System	ISO 13485:2016
Other applicable directive	ROHS Directive: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment



 Regulatory Affairs VP/Director or Designee
 Colleen Watson

13 OCT 2020

 Date and Place
 26125 N. Riverwoods Blvd.
 Mettawa, IL 60045 USA



 QA Manufacturing Site Representative or OEM
 Quality Designee
 Mark Berryhill

~~09-OCT-2020~~

 Date and Place
 1100 Bird Center Dr.
 Palm Springs, CA 92262 USA

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Attachment

Device Listing

Product Codes	Description	EU Class	Rule(s)	GMDN Code	Type of CE Marking	Technical File
777000XS	Infant Flow LP nasal prong, Single Patient Use; Extra Small. Box of 10	Class IIa	Rule 11	35202	CE 2797	90-R0222
777000S	Infant Flow LP nasal prong, Single Patient Use; Small. Box of 10	Class IIa	Rule 11	35202	CE 2797	90-R0222
777000M	Infant Flow LP nasal prong, Single Patient Use; Medium. Box of 10	Class IIa	Rule 11	35202	CE 2797	90-R0222
777000L	Infant Flow LP nasal prong, Single Patient Use; Large. Box of 10	Class IIa	Rule 11	35202	CE 2797	90-R0222
777000XL	Infant Flow LP nasal prong, Single Patient Use; Extra Large. Box of 10	Class IIa	Rule 11	35202	CE 2797	90-R0222
777002XS	Infant Flow LP nasal mask, Single Patient Use; Extra Small. Box of 10	Class IIa	Rule 11	37591	CE 2797	90-R0222
777002S	Infant Flow LP nasal mask, Single Patient Use; Small. Box of 10	Class IIa	Rule 11	37591	CE 2797	90-R0222
777002M	Infant Flow LP nasal mask, Single Patient Use; Medium. Box of 10	Class IIa	Rule 11	37591	CE 2797	90-R0222
777002L	Infant Flow LP nasal mask, Single Patient Use; Large. Box of 10	Class IIa	Rule 11	37591	CE 2797	90-R0222
777002XL	Infant Flow LP nasal mask, Single Patient Use; Extra Large. Box of 10	Class IIa	Rule 11	37591	CE 2797	90-R0222
Infant Flow LP System Kits						
7772020LP	Infant Flow LP Generator Kit includes generator, sizing guide, and small, medium, and large nasal prongs; Single Patient Use. Box of 10	Class IIa	Rule 11	37498	CE 2797	90-R0222

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7772000LP	Infant Flow LP Generator Kit without prongs.	Class IIa	Rule 11	37498	CE 2797	90-R0222
7772011	Infant Flow LP generator (7772020LP) and F&P RT132 neonatal single-limb, heated circuit; Single Patient Use. Box of 10.	Class IIa	Rule 11	37498	CE 2797	90-R0222
7772021	Infant Flow LP generator (7772020LP) and F&P RT132 neonatal single-limb, heated circuit; Single Patient Use. Box of 20.	Class IIa	Rule 11	37498	CE 2797	90-R0222
26404-001	Infant Flow LP nCPAP generator without prongs kit (7772000LP) and F&P RT132 neonatal single-limb, heated circuit; Single Patient Use. Box of 10.	Class IIa	Rule 11	37498	CE 2797	90-R0222
26405-001	Infant Flow LP nCPAP generator without prongs kit (7772000LP) and F&P RT132 neonatal single-limb, heated circuit; Single Patient Use. Box of 20.	Class IIa	Rule 11	37498	CE 2797	90-R0222
Infant Flow SiPAP Localization Kits						
27031-001	<u>Kit, O2/AIR, DISSFxDISS, b/w UK</u> Qty: 1 - CORDSET,230V,10A,2.5m,UK (type G) Qty: 1 - HOSE,O2,3m,DISSF/DISSF,W HITE Qty: 1 - HOSE,AIR,3m, DISSF/DISSF,BLK/WHT	Class IIa	Rule 2	42039 40484 47487	CE 2797	90-R0222

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GMDN Code	GMDN Term
35202	CPAP Nasal Oxygen Cannula
37591	CPAP/BPAP Nasal Mask, Single-Use
37498	Respiratory Oxygen Therapy System
42039	Oxygen Low Pressure Tubing
40484	Medical Air Low Pressure Tubing
47487	Electrical-Only Medical Device Connection Cable, Reusable
35652	Extra muscular Diaphragm/Phrenic Nerve Electrical Stimulation System