

Declaration of Conformity


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| Legal Manufacturer | Vyaire 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 |



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

29-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 |