Legal Manufacturer	Vyaire Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	PF-AN-02 Respiratory Non-Heated Circuits and Accessories
Product Codes	See Declaration of Conformity
Declaration of Conformity	DC041 and DC042

Standards and Directives Applied

Standard Number	Complete Name of Standard	Year
EN 1041	Terminology, Symbols, and information Provided with Medical Devices - Information Supplied by the Manufacturer With Medical Devices	2008 +A1 2013[a] 1998[b]
EN ISO 17510-2	Sleep apnea breathing therapy. Masks and application accessories	2009[c]
EN ISO 17510-2*	Sleep apnea breathing therapy. Masks and application accessories	2009§4.1 Annex C[d]
EN ISO 5356-1	Anaesthetic and respiratory equipment-Conical connectors—Part 1: Cones and sockets	2004[a&b] 2015[c&d]
ISO 5367	Breathing tubes intended for use with anaesthetic apparatus and ventilators	2000[a]
EN ISO 594-1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 1: General requirements	1986[a]
EN ISO 594-2	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 2: Lock fittings	1998[a]
EN 62366	Medical devices. Application of usability engineering to medical devices	2015[c&d]
EN ISO 12342	Breathing tubes intended for use with anaesthetic apparatus and ventilators	1998+A1:2009[b]
EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	2016
ISO 1000	SI units and recommendations for the use of their multiples and of certain other units	1992/Amendment 1:1998[b]
EN ISO 8185	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems	2007[b]
EN ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	2009/AC2010[a] 2003[b] 2009[c&d]
EN ISO 10993-5	Biological evaluation of medical devices. Tests for in vitro cytotoxicity	1999[b] 2009[c]
EN ISO 10993-10	Biological evaluation of medical devices. Tests for irritation and skin sensitization	2002 Amendment1 2006[b] 2010[c]

EN ISO 10993-17	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	2009[a]
EN ISO 14971	Medical Devices – Application of Risk Management to Medical Devices	2009[b] 2012[a&c]
EN ISO 15223-1	Medical Devices – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied.	2016
EN 62570	MR Safe Indications	2015[d]
EN 15986	Symbol for uses in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates	2011[a&c]
ISO 80601-2-13	Medical electrical equipment- Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	2012[a]
EN ISO 80601-2-55	Medical electrical equipment-part2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors	2011[a]
MEDDEV 2.4/1 Rev 9	Guidelines for the Classification of Medical Devices	2010
MEDDEV 2.7.1 Rev. 4	Guidelines on Medical Devices Evaluation of Clinical Data	2009
MDD	Medical Device Directive	93/42/EC – 1993 As amended by 2007/47/EC-2007 2007
NB-MED/2.5.2/Rec2	Reporting of design changes and changes of the quality system	2000

[a] Vital Signs
[b] Air*Life*
[c] NIV Mask (Private labelled product)
[d] SuperNO2VA™ Nasal PAP Ventilation Device
**Supernova masks uses this standard as a reference standard only.*

All supporting documentation is retained by manufacturer.

Colleen Watson

Regulatory Affairs VP/Director
Colleen Watson

30 April 2020

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