Legal Manufacturer	Vyaire Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	PF-AN-06 Resuscitation Devices
Product Codes	See Declaration of Conformity
Declaration of Conformity	DC047

Standards and Directives Applied

Standard Number	Complete Name of Standard	Year
EN ISO 5356-1 EN ISO 5356-1	Anesthetic and respiratory equipment-Conical connectors—Part 1:Cones and sockets	2015[a&c] 2004[b]
ISO 5362	Anaesthetic reservoir bags	2006[b&d]
EN ISO 13485	Quality management systems. Requirements for regulatory purposes	2016[a,b,&d]
EN ISO 14971	Application of risk management to medical devices	2012
EN ISO 10993-1	Biological evaluation of medical devices. Evaluation and testing within a risk management process	2009[a,b&c]
EN ISO 10993-5	Biological evaluation of medical devices. Tests for in vitro cytotoxicity	2009[a,c&d]
EN ISO 10993-10 EN ISO 10993-10	Biological evaluation of medical devices. Tests for irritation and skin sensitization	2013[a&c]
EN ISO 10993-17	Biological evaluation of medical devices. Establishment of allowable limits for leachable substances	2009[b]
*EN ISO 10651-4	Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators	2009[a,c&d]
EN ISO 10651-5	Lung Ventilators for Medical Use-Particular Requirements for basic safety and essential performance- Part 5: Gas-powered emergency resuscitators	2006[b]
EN 62366	Medical Devices – Application of usability engineering to medical devices	2015[c&d]
EN 62570	MR Safe Indications	2015[c]
EN ISO 15223-1	Symbols to be used with medical device labels, labelling and information to be supplied.	2016

EN 15986	Symbol for use in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates	2011[a,b&c]
EN 1041	Information supplied by the manufacturer of medical devices	2008+A1: 2013[a&b] 2008[c]
MEDDEV 2.4/1 Rev 9	Guidelines for the Classification of Medical Devices	2010
MEDDEV 2.12-2 Rev 8	Post Market Clinical Follow-up of Medical Devices Under The Medical Devices Directive	2013
MDD as amended	Medical Device Directive	93/42/EEC

[a] AirLife
[b] Vital Signs
[c] GaleMed (Private Labelled Product)
[d] SuperNova Nasal PAP Ventilation System

[†]Standards that apply to all three product family are not footnoted.
**Application of EN ISO 10651-4 "Particular requirements for operator powered resuscitators" was also considered for these devices. The mouth to mask resuscitators: 2K8012 and 2K8013 are not within the scope of the standards as the standard applies to devices where "ventilation of the lungs is produced by the operator compressing the compressible unit of the device".*
The remaining products do fit into the scope of the standard. After review of the standard, the testing performed and post market feedback on these devices it was not felt necessary to explicitly show conformance to EN ISO 10651-4 with the exceptions noted below, for the following reasons:

- *The Essential Requirements of the directive have been adequately addressed by internal testing and compliance to ASTM F920-85*
- *ASTM F 920 has similar requirements to EN ISO 10651-4, notably inspiratory and expiratory resistance, valve function and resistance to vomitus.*
- *Actual use has demonstrated the safety and clinical usefulness of these devices based on the low volume of complaints for these products*

Exceptions:
The marking requirements of Clause 9 of EN ISO 10651-4 have been addressed.
The instructions for use requirements of Clause 10 of EN ISO 10651-4 have been addressed.

All supporting documentation is retained by manufacturer.

Colleen Watson

Regulatory Affairs VP/Director
Colleen Watson

17 July 2020

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