Legal Manufacturer	Vyaire Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	RT-08 Active Humidification System
Product Codes	See Declaration of Conformity
Declaration of Conformity	DC059

Standards and Directives Applied

Standard Number	Complete Name of Standard	Year
EN ISO 14971	Medical devices. Application of risk management to medical devices	2012
EN ISO 13485	Medical devices. Quality management systems. Requirements for regulatory purposes	2016
EN ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009
UL 2556 §3.4	Safety for Wire and Cable Test methods	2015
EN ISO 10993-5	Biological evaluation of medical devices. Tests for in vitro cytotoxicity	2009
EN ISO 10993-10	Biological evaluation of medical devices. Tests for irritation and skin sensitization	2010
EN ISO 10993-3	Biological evaluation of medical devices. Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014
EN ISO10993-6	Biological evaluation of medical devices. Tests for local effects after implantation	2007
EN 10993-17	Biological evaluation of medical devices. Establishment of allowable limits for leachable substances	2009
EN ISO 10993-18	Biological evaluation of medical devices. Chemical characterization of materials	2009
EN ISO 5356-1[a&b]	Anesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets	2015
EN ISO 8185	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems	2009
EN 60601-1	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability 3rd edition	2006/A1 2013-3rd edition [a&b]
EN 62366	Application of usability engineering to medical devices	2008
EN ISO 5367	Anaesthetic and respiratory equipment. Breathing sets and connectors	2014[a&b]
EN 1041	Information supplied by the manufacturer of medical devices	2008+A1:2013
BS ISO 639-1	Codes for the representation of the names of languages. Alpha-2 cod	2002

BS EN ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	2016
MEDDEV 2.4/1 Rev 9	Guidelines for the Classification of Medical Device	2010
EN ISO 80601-2-12	Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	2011

a- Infant Heated Circuits
b- Adult Heated Circuits

All supporting documentation is retained by manufacturer.

Colleen Watson — 25 FEB 2020

Regulatory Affairs VP/Director
Colleen Watson

Date and Place
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