**FDA 指定认可标准**

• IEC 60601-1: 2012: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*

• IEC 60601-1-2: 2014: *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*

• IEC 60601-1-11: 2015: *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*

• Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family

• IEC 62304: 2015: *Medical Device Software – Software Life Cycle Processes*

• AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*

• ANSI/IEEE C63.27: 2017: *American National Standard for Evaluation of Wireless Coexistence*

• AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*

• ISO 10993: Fifth Edition 2018-08: *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process*

• ISO 18562-1 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process*

• ISO 10651-5 First Edition 2006-02-01: *Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 5: Gas-Powered Emergency Resuscitators*

• ISO 17510 First Edition 2015-08-01: *Medical devices -- Sleep Apnoea Breathing Therapy -- Masks and Application Accessories*

• ISO 18562-2 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter*

• ISO 18562-3 First Edition 2017: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds*

• ISO 18562-4 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate*

• ISO 80601-2-12 First Edition 2011-04-15: *Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators [Including: Technical Corrigendum 1 (2011)]*

• ISO 80601-2-13 First Edition 2011-08-11: *Medical Electrical Equipment -- Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]*

• ISO 80601-2-69 First Edition 2014-07-15: *Medical Electrical Equipment - Part 2-69: Particular Requirements for Basic Safety and Essential Performance of Oxygen Concentrator Equipment*

• ISO 80601-2-70 First Edition 2015-01-15: *Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnoea Breathing Therapy Equipment*

• ISO 80601-2-74 First Edition 2017-05: *Medical Electrical Equipment - Part 2-74: Particular Requirements for Basic Safety and Essential Performance of Respiratory Humidifying Equipment*

• ISO 80601-2-79 First Edition 2018-07: *Medical electrical equipment - Part 2-79: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Impairment*

• ISO 80601-2-80 First Edition 2018-07: *Medical Electrical Equipment - Part 2-80: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency*