

VENTILATOR PRODUCTION GUIDE

UNDERSTANDING PRODUCT QUALITY & SAFETY REQUIREMENTS

To meet the challenges of the 2019 novel coronavirus, Intertek's global medical device experts are offering advisory services, regulatory support, and state-of-the-art testing to help manufacturers quickly develop critical care devices for healthcare professionals around the world.



Manufacturing Considerations

Given the life-saving role of ventilators, ensuring that the critical care devices function as intended is critical.

This production guide provides insight into complex global requirements, using US and UK requirements as examples for major ventilator markets. We encourage manufacturers to work directly with Intertek experts to create a customised solution for their target countries.

We help at every stage, from creating testing and certification plans, to assisting with documentation requirements, to training your teams. With our "design it right the first time" expertise, you'll reduce rework and product failures, and get your products to market faster.

Contact us to immediately access ondemand expertise to accelerate your product design, reach global markets, and mitigate risk.

Ventilator Testing Requirements

US Food & Drug Administration (FDA) Emergency Use Authorization (EUA)

Per the FDA Enforcement Policy for Ventilators and Other Respiratory Devices During the Coronavirus 2019 (COVID-19) Emergency, products should meet:

- 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 & 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
- 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
- Other collateral and standards, as applicable

UK Medicines & Healthcare Products Regulatory Agency (MHRA)

Per MHRA guidance for rapidly manufactured ventilators, MHRA will take a view on the risks and benefits of the device as a whole. Where the manufacturer proposes deviations from expected standards, this should be clearly defined and evaluated within the

manufacturers' risk assessment. Given current time constraints, the MHRA recognises that full testing to standards may not be feasible; however, any areas that cannot be tested should be fully addressed within the risk assessment. Safety and performance will be assessed on a case by case basis.

The most relevant regulations are included below. These are not currently formal requirements, but many are harmonised against regulatory requirements. These should be considered as helpful advisory standards:

- BS EN 794-3:1998 +A2:2009: Particular Requirements for Emergency and Transport Ventilators
- ISO 10651-3:1997: Lung Ventilators for Medical Use – Emergency and Transport
- BS ISO 80601-2-84:2018: Medical Electrical Equipment. Part 2 to 84. Particular requirements for basic safety and essential performance of emergency and transport ventilators – especially the parts on 'patient gas pathway' safety (similar to IEC 60601)
- BS ISO 19223:2019: Lung Ventilators and Related Equipment.

Product Certification

Intertek is accredited to offer a range of certifications worldwide. [More about certification for global markets.](#)

Product Registration & Authorization Process

US FDA Requirements

Submit a pre-EUA request with information about your ventilator.

- Indicate if your device has approval in another marketplace such as the EU, Australia, Canada, or Japan.
- Provide supporting evidence that the device or design complies with applicable safety standards.
- Indicate if the device meets other FDA regulations and whether it is manufactured in compliance with QMS requirements of US 21 CFR 820 or ISO 13485 or equivalent.
- Verify the device is designed to operate on US power supply; 120 VAC and 60 Hz.
- Verify the operator interface, controls and operational manuals are provided in English

If authorized, the FDA will request supporting information and provide guidance on labelling and other aspects outlined in section 564(e)(1)(A) of the FD&C Act.

UK MHRA Requirements

Department of Health and Social Care (DHSC) specifications should be reviewed, then manufacturers may contact the DHSC for approval.

After DHSC approves a medical device, the manufacturer has the option to apply to the MHRA for an exemption from the regulations (derogation).

Product Labelling and Use Documentation Requirements

US FDA Guidance

Appropriate conditions designed to ensure that health care professionals operating the devices are informed:

- The FDA has authorised the emergency use of the device
- The operator interface, controls and operational manuals are provided in English
- Of any significant known and potential benefits and risks related to the emergency use of the device, and of the extent to which such benefit and risks are unknown
- Of alternatives to the device that are available, and of their benefits and risks

- Operations have the option to accept or refuse use of the device, of the consequence, if any, of refusing administration of the device, and of alternatives to the device available and of their benefits and risks
- Ensure that individuals to whom the device is administered are informed
- Provide means to monitor and report adverse events associated with the emergency use of the device to the FDA
- Device manufacturers are to maintain all records related to manufacturing of EUA devices and make them accessible to the FDA

Note: The FDA intends to include conditions that are consistent with those promulgated under 21 CFR Part 803.

UK MHRA Guidance

Labelling requirements are available on the MHRA website. These are updated regularly; manufacturers should always check for the most recent version.

Packaging & Shipping Requirements

The expectation is that the device arrives in the same functional condition as it left your manufacturing plant. Packaging should also keep equipment sterile, especially for components that may have prolonged skin contact.

Intertek can assist in defining the packaging requirements, establishing a test plan that demonstrates the capability of the product and packaging, including the potential impact of vibration, shock, and temperature extremes associated with shipping and handling.

Facility and Environmental Requirements and Inspections

Manufacturers would typically be assessed in accordance to the applicable requirements of ISO 13485. This will be a gap assessment in accordance to their existing quality management system. Good Manufacturing Practice (GMP) assessment- a system for ensuring products are consistently produced according to quality standards – may also apply.

Intertek can optimize existing infrastructure to streamline processes or design and construct a turnkey laboratory to meet your needs.



Components & Supply Chain

Intertek experts offer guidance on managing complex and uncertain global supply chains to mitigate risk. We can help build strategies around component selection, chemical and environmental compliance, and product management to meet changing technical and regulatory requirements in more than 100 countries.


People & Training Support

Intertek offers a suite of training services and technologies to help thoroughly and rapidly train staff on new procedures, equipment, and production goals. Your staff will become one of the smoothest parts of your manufacturing process.

About Intertek

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 46,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

FOR MORE INFORMATION

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