Application for the placing on the market a non CE-marked medical device due to COVID-19 in the interest of the protection of health

Please fill in and send this form to COVID-19-regioner-med-udstyr@dkma.dk with "*Dispensation*" in the mail subject

The manufacturer must complete this section:

Name and address of manufacturer: Aalborg University Fredrik Bajers Vej 7 K 9220 Aalborg Øst **Name and address of Authorised Representative within EU (if relevant):** Not relevant – EU based manufacturer. **Name and address of the distributor (if relevant/ known):** Not relevant – Is not distributed through a distributor
Name of device: AAU Pandemic Ventilator
Type of device: A minimal ventilator intended for crisis situations where no CE marked ventilators are available.
Device model (REF)/ Catalogue no: AAU Pandemic Ventilator, Rev. 001
Series/ LOT numbers on the label, if available Series number not currently established, will be serial starting from 1.
Number of devices and/or expected time period applied for: Until the current crisis situation is resolved.
Aspects where the medical device differentiates from other CE marked alternative medical devices available on the market: The AAU pandemic ventilator has been developed based on the guidelines provided by UK, Department of Health & Social Care. A record of the version of these guidelines that has been used for the development is provided in: VENT-20-003-BIN UK Guidelines, Rev. 001 An evaluation of these guidelines that has been used to translate them into technical requirements is provided in: VENT-20-002-DOC Guideline Evaluation Report (UK Guidelines), Rev. 001

The AAU pandemic ventilator is designed to deliver a specific ventilator mode. As such it differs from CE marked ventilators in the range of ventilation modes delivered to the patient. For that individual mode, settings are equivalent to CE marked devices. In addition, and where appropriate, comparison has been made between the functionality provided by the pandemic ventilator and a specific CE marked ventilator, illustrating the ability of the pandemic ventilator to provide the necessary functionality for this mode when compared to the CE marked device.

The tests performed on the AAU pandemic ventilator are documented in:

VENT-60-001-DOC Verification Specification & Report

Traceability is provided between the specification of the ventilator:

VENT-10-002-DOC Technical Requirements

To ensure that requirements are verified before the AAU pandemic ventilator is released.

Further information including a risk analysis, identification of hazards, estimation of risks and how such risks have been addressed, together with information to support a positive risk benefit analysis:

A top down risk analysis has been performed:

VENT-30-001-DOC Risk Analysis (Top-Down), Rev. 001

Traceability is provided between the risk analysis and the technical requirements:

VENT-10-002-DOC Technical Requirements

Unacceptable residual risks have been identified that it was not possible to mitigate. A risk/benefit analysis has been performed based on the clinical rationale provided in:

VENT-50-001-DOC Clinical Rationale, Rev. 001

Under the circumstances that the ventilator is only used in deeply sedated patients, and that no other CE marked ventilators are available, we find that the benefits is greater than risks in using the system despite the presence of unacceptable residual risks. In the case that the ventilator would not be used in aforementioned cases – the patient would die.

Information whether the product previously has been CE marked as a medical device and/ or information whether the product is placed on the marked in other countries outside EU/EEA:

Has not previously been CE marked as a medical device.

Further information, if any: (please attach any relevant information available such as instruction for use, product label, pictures etc.):

VENT-10-003-DOC Instruction For Use, Rev. 001
VENT-40-002-BIN Ventilator Demonstration Video, Rev. 001

Information on where the device will be used e.g. department, clinic, hospital, Region:

Will be determined and approved by the Danish Ministry of Health in collaboration with the Danish Regions according to need in relation to the COVID-19 crisis.

Date: 3/4-2020

Signature: 

Name (printed): Lars Hvilsted Rasmussen, dekan Det Sundhedsvidenskabelige Fakultet, Aalborg Universitet

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The healthcare professional must complete this section:

Name and address of Healthcare Institution: Name of healthcare professional: Email: Telephone:
Reason for the device's necessity due to protection of health:
Further information:
Declaration: *It is my opinion that the medical device is intended to achieve an improvement of Danish patient conditions and that there is no other CE- marked device available on the market that will fulfil the function required.* Date: Signature: Name and title (printed):