LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Authorisation of the putting into service of non-CE marked medical devices consisting of minimal respiratory ventilators intended for crisis situations on the Danish marked and which is in the interest of the protection of health.

Date: 2020-04-06
Reference: 2020034164
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E med-udstyr@dkma.dk

In reply to your application dated April 03, 2020 and your statement of the device's necessity to the protection of health documented separately and dated March 26, 2020, the Danish Medicines Agency hereby grant an authorisation for AAU to put non-CE marked respiratory ventilation systems into service for treatment of unspecified patients at unspecified hospitals in Denmark.

The medical doctors responsible for the declaration of the need for the devices are:

- Michael Braüner Schmidt, Lægefaglig direktør, Speciallæge i anæstesiologi, Aalborg Universitetshospital, Denmark and
- Lars Hvilsted Rasmussen, Dekan, Professor i Hjerte-kar-sygdomme, Speciallæge i kardiologi og intern medicin, Det Sundhedsvidenskabelige Fakultet, Aalborg Universitet, Denmark.
  E-mail: dekan-sund@adm.aau.dk

Descriptions, terms and conditions

Products: AAU Pandemic Ventilator, Rev. 001

Commercial name(s)/ brand name(s): AAU Pandemic Ventilator

Medical device class: Not specified, currently non-CE-marked

Scope: The above-mentioned medical device

Quantity: Unlimited use in Denmark

Duration:
This authorisation of the putting the AAU Pendemic Ventilator into service for the end user is valid until the Medical Devices Directive MDD 93/42/EEC is repealed by May 26, 2020. In case the implementation of the MDR will be postponed beyond August 1, 2020, the autorisation is valid until August 1, 2020.

An eventual prolongation of the authorisation will thus be according to either section 6(12) of the Danish Executive Order 1263 on Medical Devices or article 59 of the MDR 2017/745, which will require a new application.

As this authorisation is due to the ongoing COVID-19 pandemic, the devices shall be returned to AAU once the pandemic is over and at the latest by August 31, 2020, unless a prolongation has been granted by the Danish Medicines Agency.

Manufacturer of the medical device:
Aalborg University
Fredrik Bajers Vej 7 K
DK-9220 Aalborg Øst

The medical doctors Michael Braüner Schmidt and Lars Hvilsted Rasmussen has informed the Danish Medicines Agency that the devices potentially are necessary for the treatment of patients during the ongoing COVID-19 pandemic in case there are insufficient number of CE-marked alternatives available on the market.

The use of the devices is thus considered to be in the interest of protection of health and safety of the patient based on the information regarding the treatment, the needs

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of the patient and the importance of the use of the specified devices in the treatment, according to the medical doctors.

This authorisation is conditional upon your company agreeing to provide full details of any adverse incidents as well as any quality problems occurring in relation to the devices or the use of the devices.

Legal basis
This decision is made in accordance with section 6(12) of the Danish Executive Order 1263 on Medical Devices.

In special circumstances, following application, the Danish Medicines Agency may authorise the placing on the market and putting into service of a device for which the conformity assessment procedures of section 6, paragraph 1-5, have not been carried out and the use of which is in the interest of protection of health, cf. section 6, paragraph 12 of the Danish Executive Order 1263 on Medical Devices.

Sincerely,

Peter Qvist
Team manager and Senior advisor, Medical Devices, Danish Medicines Agency

Attachments:

- Application, dated April 03, 2020
- Statement of the device's necessity to the protection of health, dated March 26, 2020