



Plastomed

Systeme für Ihr Leben...

Mechanical ventilation sets / Mechanical ventilation equipment

Intended purpose

Mechanical ventilation sets and equipment

Mechanical ventilation sets and equipment are used to administer and introduce gases for mandatory ventilation and continuous spontaneous ventilation. They are part of the mechanical ventilation system and connect ventilators with patients.

Mechanical ventilation sets and equipment are single use products.

The intended user (healthcare professional e.g. attending physician, nurse) has a good expertise in using the mechanical ventilation sets and equipment. Patients and other persons are not allowed to use the ventilation set and the ventilation equipment.

Based on the patient's constitution the intended user decides which ventilation technique is necessary and which tools and equipment is used.

These products are **non-invasive single use medical devices class IIa** (sterile, non-sterile) for short term usage (Normally intended for continuous use for less than 30 days) The non-invasive devices can be connected to a medical device with the class IIa and higher.

For hygienic reasons the device is to be exchanged after usage.

Nebulizer sets

Nebulizers are used to produce aerosol. Liquids are filled into the nebulizer and sprayed into fine aerosol. The nebulizer has a connection to supply air or oxygen. An opening is provided in the nebuliser so that air or oxygen can be introduced. The aerosol produced in the nebuliser chamber is dispensed through the mouth opening and can be breathed in through an attached mouthpiece or a mask. The nebulizer set consists of the nebulizer, tubes for air/oxygen supply, mouthpiece or mask.



The intended user (attending physician, nurse, trained patients) has a good expertise in using nebulizer sets.

Based on the patient's constitution the attending physician or nurse decides which nebulizer therapy is necessary and which tools and equipment are used.

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Oxygen Tubes / Safety Tubes

Oxygen tubes and safety hoses are used to pass oxygen from the source of oxygen (central or mobile supply source) to the patient. On patients' side of spontaneous breathing patients, it is usually connected with a nasal cannula or a breathing mask during oxygen therapies. At ventilated patients it can be used to connect the mechanical ventilation device with the source of oxygen.

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Based on the patient's constitution the intended user decides which ventilation technique is necessary and which tools and equipment is used.

These products are **non-invasive single use medical devices class IIa** (sterile, non-sterile) for short term usage (Normally intended for continuous use for less than 30 days) The non-invasive devices can be connected to a medical device with the class IIa and higher.

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Flextubes

Flextubes are flexible tube systems with adapters designed for aerosol therapy together with nebulizer sets. The intended user (attending physician, nurse, trained patients) has a good expertise in using nebulizer sets. Based on the patient's constitution the attending physician or nurse decides which nebulizer therapy is necessary and which tools and equipment are used.

These products are **non-invasive single use medical devices class IIa** (sterile, non-sterile) for short term usage (Normally intended for continuous use for less than 30 days) The non-invasive devices can be connected to a medical device with the class IIa and higher.

For hygienic reasons the device is to be exchanged after usage.

Product Classification

According to rule 2:

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa: if they may be connected to an active medical device in Class IIa or a higher class **(93/42 EWG, Appendix IX, III Classification)**

The class IIa classification was made for the following reasons:

The non-invasive devices can be **connected to a medical device with the class IIa and higher** (ventilator). They are used for introduction **and administration of gases** for mechanical ventilation.