HAMILTON MEDICAL
Intelligent Ventilation since 1983

Bonaduz, July 28, 2017

Company statement

Reprocessing requirements for reusable consumables from Hamilton Medical

To whom it may concern

An appropriate reprocessing process for cleaning and disinfection, or cleaning and sterilization is essential to ensure that medical devices do not transmit infectious pathogens to patients, however not all equipment used for patient care automatically requires sterilization.

For the purposes of reprocessing, medical devices are classified[1] according to their type of application and the resulting risks. The classification is as follows:

- **Noncritical medical devices**: Surfaces that come into contact with intact skin only, and not mucous membranes (e.g., cables). As defined by the FDA, this category also includes devices that do not directly contact the patient but may become contaminated with microorganisms and organic soil during patient care (e.g. ventilators).

- **Semicritical medical devices:** Any surfaces that come into contact with mucous membranes or pathologically affected skin. Any device or component that carries gas inhaled or exhaled by the patient, such as breathing circuits, masks, expiratory valves, flow sensors, etc., falls into this category.

For **noncritical** devices, the FDA recommends thorough cleaning, then intermediate or low-level disinfection depending on the nature and extent of contamination.

For **semicritical** equipment used for patient care, the minimum requirement is high-level disinfection. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants, provided the factors influencing germicidal procedures are met.

Pasteurization (using a washer-disinfector) is a recognized alternative to high-level disinfection for respiratory therapy equipment.

Please note the following information with respect to reprocessing Hamilton Medical products:

- After reprocessing, each part must be checked to ensure it is functioning correctly and a visual test carried out. Defective products should be discarded.
- Hamilton Medical recommends strict adherence to the manufacturer's guidelines for sterilization, disinfectants and cleaning solutions.
- Immersion time for different agents might vary.
- It is the user's responsibility to ensure the validity and effectiveness of any other method which is not recommended by Hamilton Medical.

1 Spaulding Classification; see U.S. Food and Drug Administration, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. Issued on: March 17, 2015

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With kind regards

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