BRIEFING NOTE

Prepared by MGC BN 27/20 – April 2020

COVID-19 Temporary Use of Equipment Not CE Marked as Devices in Medical Gas Service

Summary

This Briefing Note is intended to support EIGA Members applying to the relevant regulatory or national health authority to allow the use of equipment not CE marked as medical equipment (to Medical Devices Directive 93/42/EEC) during the coronavirus (COVID-19) pandemic for use in medical or breathing gas service.

Situation prior to the COVID-19 pandemic

Medical devices are placed on the market in accordance with the Medical Device Directive (MDD).

With the current unprecedented demand for oxygen, EIGA Members are faced with a choice between:

- not being able to supply the demand for oxygen due to the lack of CE marked devices; or
- supplying oxygen using equipment that is not claiming compliance with the MDD regulations but is safe for use with the specific gas.

NOTE Whilst oxygen is the medical gas in greatest demand, there are other gases to which this publication may apply.

EIGA Members policy and practice is to follow all applicable regulations where they operate. This includes compliance to the requirements for CE marking regulators and associated equipment in medical gas service. With the coronavirus disease pandemic, EIGA Members are faced with unprecedented demand for oxygen and associated devices and there are insufficient CE marked devices to meet this demand. Consequently, as a short-term measure during this crisis, EIGA Members are proposing the use of devices that do not meet all these legal obligations but are fit for use in terms of safety and quality.

EIGA request relevant regulatory or national health authority to permit the temporary use of non-CE marked devices in medical service

This publication is consistent with European Commission Recommendation 2020/403 of 13 March 2020 *on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.*

The purpose of this Briefing Note is to support approaches to relevant regulatory or national health authority to grant temporary relaxation of the requirement to use only CE marked devices. However, there is no intent to relax the requirements for the devices to be fit for service in terms of quality, performance and safety.

For this briefing note the term “device” is to include, but is not limited to, the following equipment:

- pressure regulators;
- gas control panels;
- flow meters/indicators; and
- integrated valves acting as pressure regulators.

NOTE EIGA has already published Briefing Note BN 25, *COVID-19 Emergency Measures to Maintain Continuous Supply of Medical Gases*.

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Priorities for the use of device in medical service

The recommended hierarchy for the use of devices for medical gas service is:

1) Medical devices that are compliant with European Union regulations, for example, cylinder pressure regulators complying with ISO 10524-1, line or manifold regulator complying with ISO 10524-2 or VIPRs complying with ISO 10524-3;

   If this is not achievable then;

2) Medical devices that are not CE Marked, but approved under a non-European Union health authority, for example, cylinder pressure regulators complying with CGA E-7, line or manifold regulator complying with CGA E-4 or CGA E-7, or VIPRs complying with CGA E-18;

   It is strongly requested that the EU Commission issues a temporary derogation from MDD for other regions under which equipment can be imported into the EU by listing recognised bodies/authorities, for example US Food and Drug Administration (FDA).

   If this is not achievable then;

3) Non-medical devices that are approved for the intended product under European Union regulations, for example cylinder pressure regulators complying with ISO 2503, line or manifold regulator complying with ISO 7291 or VIPRs complying with ISO 22425;

   If this is not achievable then;

4) Non-medical devices that are approved by a recognised body for the intended product under non-European Union regulations, for example from China, Japan or North America.

Selection of devices

It is the company's responsibility to undertake a risk assessment for the device.

The risk assessment shall be performed for a defined intended use. Included in the assessment shall be consideration of the compatibility between the supply devices and use equipment, for example flowrate and pressure, see guidance below.

The risk assessment shall be retained as a written document. The permission to use a device shall be for a defined limited time period for the duration of the pandemic and these permissions shall be reviewed on a periodic basis.

Guidance for performing risk assessment:

- **Flowrate:**
  - The flowrate can be significantly greater for a technical device than a medical device and may not have an inbuilt flow regulation. Flowrates for individual cannulas are typically between 2 and 6 litres per minute, high flow rates can be hazardous to the patient. Depending upon the purpose of the device, cannula or bulk supply to equipment, it could be necessary to limit the flow.

    If the maximum flow rate at the outlet of the device is too great for downstream equipment, a flow limiting device (orifice or other) shall be considered.

- **Pressure at outlet:**
  - The range of selectable pressure could be significantly greater for a technical device than a medical device. The user shall check that the delivered pressure is not excessive for the equipment used.

    Alternate devices shall not have an adjustable delivery pressure range of more than 10 bar.

    If there is need for a device that delivers more than 10 bar, then additional measures shall to be taken to reduce the risk to the patients.[1]

[1] In this publication bar shall indicate gauge pressure unless otherwise noted i.e., (bar, abs) for absolute pressure and (bar, dif) for differential pressure.

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- **The pressure protection of the patient:**
    - Check that the delivered pressure is not excessive for the application, pressure relief devices may be required.
- **Connections**
    - In the case of different outlets, it may be necessary to use adaptors to connect or to change the user's equipment, for example, nitrogen thread compared to oxygen thread.
- **Usability:**
    - Physical size.
    - Alignment of connections.
    - Units of measure for gauges and flow indication can differ.
    - Consideration of the potential misuse or failure to understand the operation by the user.
- **Labelling and precautionary instructions:**
    - Labels may be different from normally seen on medical devices.
    - Additional labels may be appropriate, for example:
        - "*OPEN CYLINDER VALVE SLOWLY AND STAND TO ONE SIDE*";
        - "*ATTENTION – TEMPORARY MEDICAL USE DURING COVID-19*"; or
        - "*TEMPORARY MEDICAL SERVICE COVID-19*"
- **Training of user:**
    - The user could require additional training as the equipment can differ from the normal medical device.
    - A written instruction for the user may be provided in order to explain any unanticipated differences from normal medical devices.
    - Any additional residual risks shall be explained.
- **Materials of construction**
    - Materials of construction shall be reviewed for the potential risk to the patient, noting that the industrial equipment does not follow the same requirements as the medical equipment.

      Guidance on the selection of non-metallic materials in oxygen service is given in EIGA Doc 73, *Use of Non-Metallic Materials in High Pressure Oxygen Breathing Gas Applications.* Within this document there is a statement:

      "When taking into account both the mechanical requirements and their toxicity in a fire, the selection of the correct non-metallic materials sometimes results in a choice between two conflicting requirements: either use a less ignitable material with higher toxicity potential or use a more easily ignitable material with lower toxicity potential."

      EIGA members have concluded that the device for use in oxidising gas service shall have:
        - passed an adiabatic compression test (oxygen pressure surge test) where the oxygen inlet pressure greater than 30 bar (for inlet pressure less than 30 bar, it is not required);
        - lubricants that comply with compatibility requirements for the oxidising gases at working pressure; and
        - been cleaned for oxygen service.

For example, if a technical grade nitrogen / argon regulator meets all of the requirements above, it can be used in medical oxygen service as described in this document.

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