Bolzano, May 29, 2025

Subject: Clarifications regarding the compliance of BSU devices produced by Oscar Boscarol Srl

In accordance with the European Medical Devices Regulation (MDR 745/2017), Oscar Boscarol Srl specifies, in the technical documentation of its devices and in the instructions for use, the activities and timelines that must be respected by the end user to ensure proper maintenance and consequently the maintenance of the device's "operating life".

It should be noted that, for a medical device, the entire device is understood to include the respective accessories (for example, bracket and power supply in the case of Oscar Boscarol's Medical Suction Devices).

In this regard, it is deemed appropriate to place greater emphasis on the following aspects:

- **Lifespan of BSU devices:**
  For Oscar Boscarol Srl's secretion suction devices (BSU), the lifespan is fixed at a period of 10 years from the production date. The device must therefore be replaced after a 10-year period from the production date.
  If the customer decides not to replace the device within this timeframe, the manufacturer would bear no responsibility for the device. A device that has exceeded the 10-year lifespan can no longer be considered compliant with the structural, safety, and performance requirements defined by the manufacturer.
  Therefore, if incidents or adverse events occur associated with the use of a device that has exceeded the 10-year lifespan, the responsibility for what happened would fall exclusively on the device's owner and not on the manufacturer.

- **Use of non-original spare parts:**
  Any component assembled on BSU devices and not matching the manufacturer's specifications results in loss of conformity of the device.
  If a non-original replacement part is identified on the device, the manufacturer would be released from any responsibility toward the device as it can no longer be considered compliant with the structural, safety, and performance requirements defined by it.

- **Maintenance timelines for BSU devices:**
  Subjecting medical devices to scheduled maintenance or on request is NOT discretionary for the user; it is a necessity and an obligation.
  Any use of the device and its components and/or accessories that deviates from the manufacturer's prescriptions compromises the product's conformity and safety and constitutes, in all respects, an alteration of a medical device, prosecutable by law.
  In particular, Oscar Boscarol Srl defines the following maintenance activities as mandatory to be performed on its BSU devices and accessories:

- **ANNUAL TEST:** this test checks whether the device fully complies with the original production characteristics and is therefore suitable for field use.
- **PERIODIC SAFETY INSPECTION:** this test must be performed every 2 years from the date of manufacture of the device and helps extend its useful life of the device, its intrinsic safety and performance.

The ACCESSORIES (bracket and power supply) are part of the device and must always be inspected in association with the device following the methods defined by the manufacturer.

The detail of the operations to be carried out during periodic safety inspection is reported in the service manuals of each device and available to both our internal service department and our authorized service centers. In general, it includes:

- Check of the container and its integrity
- Check for loose, poorly secured, or broken internal parts
- Global functionality check of the device connected to its accessories (power supply and/or support bracket and power)
- Battery replacement
- Replacement of all flexible vacuum tubes
- Check of the vacuum gauge and its functionality
- Check of the vacuum regulator and its functionality
- Replacement of the device charging contacts and the support bracket
- Replacement of the carrying bag (if necessary)
- Sterilization of the autoclavable secretion bottle or the secretion collection container for the version with single-use liner
- Labeling and readability check of the labels
- Battery recharge check with the power supply (included or, if not available, via the included power supply)
- Battery recharge check via the support bracket
- Check of the indicator lights
- Check of the activation switch
- Check of the maximum suction value
- Replacement of the sealing rings of parts determining the IP protection degree
- Final test checks including the electrical safety test performed with the power supply provided with the device or, if unavailable, with the power supply provided to the authorized service center
- Communication to the manufacturer of the technical intervention through the preparation of the test report and the completion of the forms (date, serial number, center that performed the maintenance)

Therefore, if such timelines are not respected, for example by avoiding performing even just one of the periodic safety inspections planned every two years, any liability of the manufacturer towards the device itself would lapse as it can no longer be regarded as compliant with the structural, safety and performance requirements defined by it and with its CE marking

Thank you for your attention and I remain available for further clarifications.
Yours sincerely

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