ATMOS MedizinTechnik GmbH & Co. KG · 79853 Lenzkirch

ATMOS MedizinTechnik
GmbH & Co. KG

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Cert. EN ISO 13485

Ihre Zeichen, Ihre Nachricht vom Your reference, dated	Ihr ATMOS Partner Your ATMOS Partner	Direktwahl Telefon / Fax Direct line Phone / Fax	Datum Date
	[redacted]		4. November 2024

Important Safety Notice:
Corrective Action in the Market for a Medical Device

Reference CA240064

Manufacturer
ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch

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atmos@atmosmed.de

Addressee
Users and operators, as well as sales partners

Identification of the affected medical devices:

- BORA UP 2080 OP 230V 50/60 Hz
  - REF: HM57522301
  - UDI-DI: 04250365183320

Affected serial numbers:

- ID-Nr.: 1103932
- ID-Nr.: 1103933
- ID-Nr.: 1103934
- ID-Nr.: 1103935

Dear Sir or Madam,

Quality and safety are our highest priorities. Therefore, we aim to act consistently and transparently as usual and request that you implement this corrective action as part of your duty to cooperate under medical device legislation, so that users can continue to use our products safely on patients.

1. **Problem Description and Cause:**
   Due to the transport of the product, a potentially faulty assembly may cause the PE protective conductor to become detached within the device.

2. **What risk exists for the patient, user, or third parties?**
   Due to risk-minimizing measures already implemented in the product, there is no danger from mains voltage for the patient, user, or third parties, even if the PE protective conductor cable becomes detached. Therefore, there is no risk of the patient, user, or third parties suffering harm (electric shock, burns, heart problems, bodily injuries, neurological damage).

3. **What actions should the addressee take?**
   Please send the potentially affected devices to ATMOS MedizinTechnik GmbH & Co. KG for verification of the protective conductor function by **November 30, 2024**. Your designated ATMOS contact person will coordinate the details of the process with you personally.

4. **Forwarding the information described here**
   Please ensure that all users of the aforementioned products and other persons to be informed are aware of this safety information. If you have passed the products on to third parties, please forward a copy of this information or inform the contact person listed below.

5. **Contact Person**
   If you have any questions or need assistance, you can contact us directly at any time:

   - Contact person: Sebastian Dopf
   - Position: Product Manager
   - Phone: +49 7653 689-653
   - Email: SDopf@atmosmed.de

Best regards

ATMOS MedizinTechnik GmbH & Co. KG

[redacted]