MDS BV
Jeverweg 2-5
9723 JE Groningen
Niederlande

Cologne, 30 July 2020

Urgent safety notification on HUMIDOBAC® HME sterile (bacterial and viral filter; REF 46830)

Dear customer,

See the attached Appendix for Urgent Safety Information on HUMIDOBAC® HME sterile (bacteria and virus filter; REF 46830).

If the affected item is still in your possession, please request a DHL return slip via our returns department for a free return shipment:

Phone: +49 2203-2980-305
Fax: +49 2203-2980-536
E-mail: Retoure@fahl.de

In order to comply with traceability legislation, please complete the attached acknowledgement of receipt in full and send it to us by one of the means indicated.

Yours sincerely

.....

.....

Urgent Safety Information

concerning
HUMIDOBAC® HME sterile
(bacteria and virus filter; REF 46830)

30 July 2020

Sender:
…….
…….
August-Horch-Straße 4a
51149 Köln / Germany

Addressees:
End consumers, users and distributors

Identification of the medical devices concerned:

Product name:	HUMIDOBAC® HME **sterile**
Item No. (REF):	**46830**
Batch No. (LOT):	11.06.2019, 17.06.2019, 24.06.2019, 11.11.2019, 09.12.2019, 08.01.2020, 07.01.2020, 20.01.2020, 14.04.2020, 15.04.2020

Description of the problem including the identified cause:
Die Andreas Fahl Medizintechnik - Vertrieb GmbH carries out a preventive product recall of the above mentioned medical devices. So far, there have been no user complaints from the field regarding the potentially affected batches.

According to information from a supplier, the housing of the bacteria and virus filter could possibly not allow the specified air flow for production-related reasons. This could result in the fact that necessary ventilation is not possible or only possible to a limited extent and, in combination with a failed alarm or insufficient monitoring, could cause serious damage to health or death.

What measures must be taken by the addressee?
Please carry out the following measures:
1. Identification of the products in your institution / company
2. Do not use the above mentioned products with immediate effect
3. Ensuring continuous care of ventilated patients
4. Separate the products and return them to the manufacturer

Please ensure in your organization that all users of the above mentioned product and other persons to be informed are aware of this Urgent Safety Information. Please fill out the attached confirmation form completely and send it back.

If you have given the products to a third party, please forward a copy of this information. We thank you in advance for your cooperation and ask for your understanding.

Contact person:
…….
Phone: +49 2203 2980 - 584

……
……

ANDREAS FAHL
MEDIZINTECHNIK-VERTRIEB GMBH

August-Horch-Straße 4a
51149 Köln, Germany

Telefon +49(0)2203/2980-0
Telefax +49(0)2203/2980-100
mail vertrieb@fahl.de
www.fahl.de

Urgent Safety Information

concerning
HUMIDOBAC® HME sterile
(bacteria and virus filter; REF 46830)

Acknowledgement of receipt

Dear Sirs,

We thank you in advance for your cooperation and ask you to fill out this document and return it to your responsible contact person of Andreas Fahl Medizintechnik - Vertrieb GmbH or via one of the following options:

- Postal return: by means of the enclosed postage paid envelope
- E-mail: sicherheitsinformation@fahl.de
- Fax: +49 2203-2980-4584

I hereby confirm receipt of the Urgent Safety Information concerning the medical device HUMIDOBAC® HME **sterile (REF 46830)** dated 30th July 2020.

□ This Urgent Safety Information has been understood and communicated to all users of the product and other persons to be informed.
□ All potentially affected products are still available. They have not been passed on to third parties.
□ There are still_____pieces of the potentially affected products available.
□ ____ units of the potentially affected products have already been delivered to third parties. We will inform the customer group/users who have receivedany of the batches mentioned about the preventive recall.
□ The potentially affected products are no longer available. We will inform the customer group/users who have received one of the batches mentioned above, inform them of the preventive recall.

Sender:

MDS BV
Jeverweg 2-5
9723 JE Groningen
Niederlande

_____
Name, first name

_____
Position

_____
Date, Signature