

■ **HUM GmbH**, Zum Pier 79, D-44536 Lünen

Important Safety Notice

Update of the instructions for use AEROpart[®] - O₂-cannula B

Sender: HUM Gesellschaft für Homecare und Medizintechnik mbH

Adressee: Users, operators and trade partners

Affected medical devices

AEROpart[®] - O₂-cannula B, oxygen cannula B, adults, cannula with ear pieces and 1,5 m (5 ft.) supply tubing

Article no.	Article description
HSB01-B	AEROpart [®] - O ₂ -cannula B, oxygen cannula B, adults, cannula with ear pieces and 1,5 m (5 ft.) supply tubing, straight nasal tips

■ **Deutschland | Germany**
HUM Gesellschaft für Homecare
und Medizintechnik mbH
Zum Pier 79 | D-44536 Lünen
FON +49 (0)231 880885-0
FAX +49 (0)231 880885-58
E-Mail: sales@hum-online.de
Internet: www.hum-online.de

■ **Büro China | Office China**
HUM Homecare and Medical Technology
A45 F9 North Tower, Poly V Mansion
Xiancun RD 11, Pearl River New City, Tianhe District
Guangzhou, 510627 Guangdong, China
FON +86 20 66691812
FAX +86 20 66691812 999
E-mail: china-office@hum-online.de

■ **IK-Nr. | Code of the institution**
330 592 869
Ust.-ID-Nr. | Sales Tax Identification Number
DE180373438
Registergericht | Commercial Register Number
Dortmund HRB 17477
Geschäftsführer | General Manager
Dietmar Uhlenbruch

■ **Bankverbindung | Bank Account**
Sparkasse Dortmund
BLZ 440 501 99
Konto 491 006 250
IBAN: DE28 4405 0199 0491 0062 50
BIC/SWIFT: DORTDE33XXX
WEEE-Reg.-Nr: DE 55961085

■ **HUM GmbH**, Zum Pier 79, D-44536 Lünen

Dear Ladies and Gentlemen,

In order to ensure the safety of our medical devices, we request that you implement the corrective measures described below as a part of your obligation to cooperate in accordance with the medical device implementation legislation, so that users can continue to use our medical devices safely on patients.

Problem Description

When checking our instructions for use for the product **AEROpart[®] - O₂-cannula B**, it was found that important user information is missing. It is extremely important that users are made aware of the information that has been added to the new instruction for use.

- The device must be connected and activated by qualified personnel.
- The product is intended for single patient use only.
- The connection of the O₂-cannulas is described.
- The checking of the connections is described.
- The „keep away from fire“ notice is added.
- A note on disposal has been added.
- The manufacturer's symbol has been included in the symbol explanation.

Risk for the Patient

No patient injuries have been reported to us so far. Nevertheless, we decided to take this voluntary measure because the safety of your patients is our top priority.

■ **Deutschland | Germany**
HUM Gesellschaft für Homecare
und Medizintechnik mbH
Zum Pier 79 | D-44536 Lünen
FON +49 (0)231 880885-0
FAX +49 (0)231 880885-58
E-Mail: sales@hum-online.de
Internet: www.hum-online.de

■ **Büro China | Office China**
HUM Homecare and Medical Technology
A45 F9 North Tower, Poly V Mansion
Xiancun RD 11, Pearl River New City, Tianhe District
Guangzhou, 510627 Guangdong, China
FON +86 20 66691812
FAX +86 20 66691812 999
E-mail: china-office@hum-online.de

■ **IK-Nr. | Code of the institution**
330 592 869
Ust.-ID-Nr. | Sales Tax Identification Number
DE180373438
Registergericht | Commercial Register Number
Dortmund HRB 17477
Geschäftsführer | General Manager
Dietmar Uhlenbruch

■ **Bankverbindung | Bank Account**
Sparkasse Dortmund
BLZ 440 501 99
Konto 491 006 250
IBAN: DE28 4405 0199 0491 0062 50
BIC/SWIFT: DORTDE33XXX
WEEE-Reg.-Nr: DE 55961085

■ **HUM GmbH**, Zum Pier 79, D-44536 Lünen

Corrective Measures

The enclosed instructions for use has missing application and safety instructions for using the

AEROpart® - O₂-cannula B.

Therefore the following corrective measures must be carried out:

- Please check your inventory and block all affected products immediately until the measures are implemented.
- Completely fill out the attached response form, even if you no longer have the affected products in stock.
- If you have passed on affected items to a third party, please ensure that your customers are promptly informed of this recall by forwarding this letter. Your customers also have to fill out the reply form and send it back to us.

Based on the data on the answer sheet, we will immediately send you a corresponding number of updated instructions for use and polybags.

- Please pack the unopened product in the sent polybag. Insert the new instructions for use **ID 885974 Rev. 6.0 | 10.01.2022** into the new outer packaging.

Please implement these measures **IMMEDIATELY!**

We require a response from each notified customer. Therefore, please send us the completed reply form until February 28, 2022.

We feel sorry for the inconvenience caused to you by this action and ask for your understanding for this measure.

Please contact us at the contact provided if you have any questions regarding this letter and its implementation.

Contact: Melissa Korf, Tel.: +49 231 88 08 85-63, E-Mail: korf@hum-online.de

Best regards

HUM
Gesellschaft für Homecare
und Medizintechnik mbH



Dietmar Uhlenbruch
CEO



i.A. Melissa Korf
Quality Management

■ **Deutschland | Germany**
HUM Gesellschaft für Homecare
und Medizintechnik mbH
Zum Pier 79 | D-44536 Lünen
FON +49 (0)231 880885-0
FAX +49 (0)231 880885-58
E-Mail: sales@hum-online.de
Internet: www.hum-online.de

■ **Büro China | Office China**
HUM Homecare and Medical Technology
A45 F9 North Tower, Poly V Mansion
Xiancun RD 11, Pearl River New City, Tianhe District
Guangzhou, 510627 Guangdong, China
FON +86 20 66691812
FAX +86 20 66691812 999
E-mail: china-office@hum-online.de

■ **IK-Nr. | Code of the institution**
330 592 869
Ust.-ID-Nr. | Sales Tax Identification Number
DE180373438
Registergericht | Commercial Register Number
Dortmund HRB 17477
Geschäftsführer | General Manager
Dietmar Uhlenbruch

■ **Bankverbindung | Bank Account**
Sparkasse Dortmund
BLZ 440 501 99
Konto 491 006 250
IBAN: DE28 4405 0199 0491 0062 50
BIC/SWIFT: DORTDE33XXX
WEEE-Reg.-Nr: DE 55961085

■ **HUM GmbH**, Zum Pier 79, D-44536 Lünen

Response Form

Exchange of the instructions for use AEROpart[®] - O₂-cannula B

Please fill out this reply form and send it to us by e-mail, fax or post to:

E-Mail: qualitymanagement@hum-online.de

Fax: +49 231 880 885 58

Post: HUM Gesellschaft für Homecare und Medizintechnik mbH
Zum Pier 79
44536 Lünen

- ☐ **We hereby confirm receipt of the letter. We have read and understood the content and will implement all measures immediately. All users and operators of the product and other persons to be informed have received the letter.**

Please fill our completely in block letters:

Sender: _____

Address: _____

Contact person: _____

Telephone No: _____ Fax No: _____

Date/Signature: _____

- ☐ **We still have _____ pieces of the AEROpart[®] - O₂-cannula B in stock.**
- ☐ **We no longer have this product in stock.**

■ **Deutschland | Germany**
HUM Gesellschaft für Homecare
und Medizintechnik mbH
Zum Pier 79 | D-44536 Lünen
FON +49 (0)231 880885-0
FAX +49 (0)231 880885-58
E-Mail: sales@hum-online.de
Internet: www.hum-online.de

■ **Büro China | Office China**
HUM Homecare and Medical Technology
A45 F9 North Tower, Poly V Mansion
Xiancun RD 11, Pearl River New City, Tianhe District
Guangzhou, 510627 Guangdong, China
FON +86 20 66691812
FAX +86 20 66691812 999
E-mail: china-office@hum-online.de

■ **IK-Nr. | Code of the institution**
330 592 869
Ust.-ID-Nr. | Sales Tax Identification Number
DE180373438
Registergericht | Commercial Register Number
Dortmund HRB 17477
Geschäftsführer | General Manager
Dietmar Uhlenbruch

■ **Bankverbindung | Bank Account**
Sparkasse Dortmund
BLZ 440 501 99
Konto 491 006 250
IBAN: DE28 4405 0199 0491 0062 50
BIC/SWIFT: DORTDE33XXX
WEEE-Reg.-Nr: DE 55961085