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**Urgent safety notice**

Recall  
concerning

TRACHEOCUR<sup>®</sup> HME-Cassette high flow, Item No. T136007 and BMV<sup>®</sup> Filterkassette high flow,  
Item No. 136007

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To all speciality retailers, other distributors, users and patients:

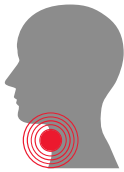
**Identification of the affected medical devices:**

HME (Heat Moisture Exchanger, also called artificial nose)

- TRACHEOCUR<sup>®</sup> HME-Cassette high flow, Item No. T136007
- BMV<sup>®</sup> Filterkassette high flow, Item No. 136007

The following batch numbers are affected:

- 201903



## **Description of the problem including determined cause:**

Recently we, the BMV Bender Medical Vertrieb GmbH, had to recall the above-named medical devices first placed on the market by us.

On the one hand, the medical devices were delivered with instructions for use that are out-of-date. On the other hand, we've had some changes in the production process of the products, which aren't yet authorized by our notified body. Therefore, products that shouldn't have been delivered.

An increased risk for patients, users and third parties is not expected. The above-named products should not be used nonetheless.

The above-named batch number should not be delivered anymore, it should be blocked for delivery and send back to the manufacturer.

If patients notice a change in their health status while or after using the products, please consult a doctor.

The recall is expected to be completed until 01 April 2019.

## **Contact:**

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