



Urgent Safety Information

Product Recall

Regarding
Bacteria and virus filter without HME
Bacteria and virus filter with HME

07/20/2020

Addressor:

Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt

Addressee:

Users, distributors, hospital logistics, representatives for medical device safety

Identification of the products concerned:

Article Reference Number	Designation
21218	Bacteria and virus filter without HME
21219	Bacteria and virus filter with HME
13162	Bacteria and virus filter without HME

The following batches are affected:

21218 Bacteria and virus filter without HME	21219 Bacteria and virus filter with HME	13162 Bacteria and virus filter without HME
10.07.2019	05.06.2020	16.09.2019
15.07.2019	11.06.2020	04.11.2019
17.07.2019	17.06.2020	16.12.2019
05.08.2019	10.07.2019	08.01.2020
12.08.2019	15.07.2019	13.01.2020
09.09.2019	14.08.2019	
07.10.2019	21.08.2019	
09.10.2019	04.09.2019	
16.10.2019	16.09.2019	
06.11.2019	17.09.2019	
11.11.2019	23.09.2019	
25.11.2019	09.10.2019	
02.12.2019	16.10.2019	
04.12.2019	23.10.2019	
23.12.2019	18.11.2019	
20.01.2020	27.11.2019	



21218 Bacteria and virus filter without HME	21219 Bacteria and virus filter with HME	13162 Bacteria and virus filter without HME
03.02.2020	04.12.2019	
10.02.2020	18.12.2019	
17.02.2020	08.01.2020	
04.03.2020	15.01.2020	
09.03.2020	20.01.2020	
11.03.2020	10.02.2020	
07.04.2020	12.02.2020	
08.04.2020	17.02.2020	
14.04.2020	24.02.2020	
	11.03.2020	
	16.03.2020	
	06.04.2020	
	08.04.2020	
18.05.2020	27.04.2020	
20.05.2020	28.04.2020	
25.05.2020	04.05.2020	
27.05.2020	06.05.2020	
	25.05.2020	
	08.06.2020	
	10.06.2020	

Description of the problem including the identified cause:

We have been informed of a serious incident and cannot completely rule out the involvement of one of our bacteria and virus filters. The serious incident occurred at the beginning of the ventilation of a patient. Ventilation was not possible.

According to the current state of information, the bacteria and virus filter used was not completely permeable. This can lead to limitation or impossibility of necessary ventilation.

If a bacteria and virus filter that is not completely or only partially permeable is used during ventilation and the monitoring of the airflow described in the instructions for use is not taken into account until the parameters are set to a stable level, in some circumstances this can lead to the following:

- brain damage,
- Cardiac and circulatory arrest,
- Death

Based on the above facts, we carry out a voluntary recall.

What measures are to be taken by the addressee?

Please carry out the following actions:

1. identification of the products in your institution / company
2. withdrawal the stock of products completely from any kind of use
3. separation of the products and make them available for collection

Primed® Halberstadt Medizintechnik GmbH*Ihr Partner in Medizin und Kunststofftechnik*

Domplatz 34 • 38820 Halberstadt



We ask you to include the safety note on the affected bacteria and virus filters in your documentation. We also ask you to kindly forward the safety instructions to other clinics and departments that have received the affected bacteria and virus filters.

Please fill out the attached acknowledgement of receipt form completely and return it to us. Keep yourself informed about this notification and the measures taken in connection with it.

Contact person:

Steffen Schaefer

(Safety Officer Medical Devices)

Phone: 03941 668 748

e-mail: steffen.schaefer@primed-halberstadt.de

With kind regards.



Steffen Schaefer

(Safety Officer Medical Devices)

Postanschrift/ Postal address: Sitz der Gesellschaft/
 Primed Halberstadt Registered office:
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 Telefax/ Fax: +49 39 41 245-65
 Internet/Web: www.primed-halberstadt.de
 E-mail/ email: primed@primed-halberstadt.de

Geschäftsführer/
 Managing director:
 Sascha Leibitzki
 Registergericht/
 Register court:
 Amtsgericht Stendal
 HRB 100724

Harzer Volksbank eG
 BLZ: 800 635 08 / Konto-Nr.: 3023 0250 00
 IBAN: DE97 8006 3508 3023 0250 00
 BIC: GENODEF1QLB

HypoVereinsbank Magdeburg
 BLZ: 200 300 00 / Konto-Nr.: 648 3326 25
 IBAN: DE58 2003 0000 0648 3326 25
 BIC: HYVEDEMM300

Es gelten ausschließlich unsere Allgemeinen Geschäftsbedingungen!
 Our general terms and conditions apply exclusively!

Ust.-Id.-Nr. DE 139375138
 Rev. 6/ 2017-01-27

Primed® Halberstadt Medizintechnik GmbH*Ihr Partner in Medizin und Kunststofftechnik*

Domplatz 34 • 38820 Halberstadt

**RE: Safety Note / acknowledgement of receipt**Dear Madam,
Dear Sir,

we thank you in advance for your cooperation and ask you to fill out this document and return it to your local Primed Halberstadt Medizintechnik GmbH representative or via one of the following options:

Fax: +49 (0) 3941 - 245 65

E-mail: steffen.schaefer@primed-halberstadt.de

Mail:

Primed Halberstadt Medizintechnik GmbH

Straße des 20. Juli 1

38820 Halberstadt

Germany

Acknowledgement of receipt:

I acknowledge receipt of the safety note issued by Primed Halberstadt Medizintechnik GmbH. I understand the information and have passed it on to all responsible employees, departments and facilities on which this measure may have an effect.

After carrying out the above measures, we come to the following conclusion:

Please check/mark the relevant box

- We have the full quantity in stock. There was no transfer to third parties.
- We have the following number of affected products in stock: _____ Pieces.
- _____ pieces of the specified product have already been passed on to third parties. We will inform the customers who have received the above mentioned product(s) about the recall.
- We have no stock of the products concerned in our warehouse and will inform our customers who have received the above mentioned product(s) of the recall.

Name, Surname

Company

Department/Position

Signature

Date

Postanschrift/ Postal address: Sitz der Gesellschaft/
Primed Halberstadt Registered office:
Medizintechnik GmbH Straße des 20. Juli 1
Domplatz 34 D-38820 Halberstadt
D-38820 Halberstadt
Telefon/ Phone: +49 39 41 668-6
Telefax/ Fax: +49 39 41 245-65
Internet/Web: www.primed-halberstadt.de
E-mail/ email: primed@primed-halberstadt.de

Geschäftsführer/
Managing director:
Sascha Leibitzki

Registergericht/
Register court:
Amtsgericht Stendal
HRB 100724

Harzer Volksbank eG
BLZ: 800 635 08 / Konto-Nr.: 3023 0250 00
IBAN: DE97 8006 3508 3023 0250 00
BIC: GENODEF1QLB

HypoVereinsbank Magdeburg
BLZ: 200 300 00 / Konto-Nr.: 648 3326 25
IBAN: DE58 2003 0000 0648 3326 25
BIC: HYVEDEMM300

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