

Heinz Meise GmbH · Medizintechnik · Im Gewerbepark 6 · 58579 Schalksmühle

Cablon Medical
Yvonne Verdam
Klepelhoek 11
3833 GZ Leusden
Netherlands

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58579 Schalksmühle
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Ihr Zeichen

Ihre Nachricht vom

Unser Zeichen

Schalksmühle, den

09.02.2018

Batch recall

Product number: AV 292.1

Batch number: 600 07 17

Dear Sir or Madam,

Meise GmbH would like to inform you about a voluntary batch recall of the product AV 291.1 with the batch no. 600 07 17. We received a complaint regarding a leaking system. The leakage was caused by a faulty bonding at the arterial chamber which is provided from a supplier.

Possible hazards

An undetected leaking System could lead to hypovolaemia (reduced circulating blood volume). It could also lead to delays and interruptions if the problem is detected prior to the start of the treatment.

Corrective actions

Meise GmbH will make sure that suitable corrective and preventive measures at the production of the supplier are taken to prevent the reoccurrence of the fault.

Measures we would like you to take

We would like you to perform the following steps:

1. Locate and remove all affected products from your institution. The product and batch number can be found on the product and the packaging.
2. Please confirm that you have received this information by filling in the reply form in the annex, and send it back to Meise Medizintechnik Fax No. +492355/909590, even if you don't have any of the affected batches left. When we receive the form, we will contact you to organize the recall and the creation of the credit note.
3. Please forward this information to all affected departments of your institution, so that they are also informed about the batch recall. If you have any further questions don't hesitate to contact us under +492355/909550 or send us an e-Mail to mail@meise.com.

The competent authority was informed about the batch recall.

We would like to apologize for the inconvenience that might have occurred to you and your staff.



Bankverbindungen: [BLZ] [Kto.-Nr.]
Sparkasse Lüdenscheid BIC WELADED1LSD, IBAN DE59 4585 0005 0004 0651 73
Märkische Bank Hagen BIC GENODEM1HGN, IBAN DE04 4506 0009 0034 8015 00
Postbank Dortmund BIC PBNKDEFFXXX, IBAN DE80 4401 0046 0231 5884 63
Commerzbank Lüdenscheid BIC COBADEFF458, IBAN DE80 4584 0026 0660 0043 00
MwSt.-Id.-Nr.: DE811227863

Gerichtsstand:
Registergericht Iserlohn
HRB 5011
Geschäftsführer:
Dipl.-Ing. Heinz Meise

Batch recall

Annex 1

Reply form

Blutschlauchsystem AV292.1

Please send the form to the following number

+492355/909590

Meise Medizintechnik GmbH Schalksmühle

Name and address of the institution

Cablon Medical
Yvonne Verdam
Klepelhoek 11
3833 GZ Leusden
Netherlands

We have received the letter regarding the voluntary batch recall of the product AV 291.1 with the batch no. 600 07 17. We have followed the instructions given and informed all departments.

- We don't have any products of the specified batch number in our stock.
- We have the specified batch number in our stock and make them available for recall.

Product no.	
Batch no.	
Use before date	
Amount of products	
Amount of packaging	

Filled in by: _____ Position: _____

Telephon: _____

Signature: _____ Date: ____/____/____