

Xenios AG . Im Zukunftspark 1 . 74076 Heilbronn . Germany



Contact person:

Thomas Junesch

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E-Mail: vigilance@xenios-ag.com

Heilbronn, 07.06.2019

Field Safety Notice for deltastream DP3 pump head

Dear valued customer,

Hereby we issue a Field Safety Notice for:

Products concerned

Product name	Article no.	Batch no.
Support.set Säuglinge, hilite 800 LT, rheoparin beschichtet, Modell Medos	MEH2C4024 (30000074)	190104M354

Problem description

The pump head gluing procedure is not fulfilling our standards.

Therefore at the moment a proper and safe use cannot be guaranteed for the batch listed above.

Action required to recall affected products

We advise you to process as follows:

- Please check your stock for the relevant products.
- Return all remaining stock of this product immediately.
- Fill out the list enclosed in the reply form and send it back to us.

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info@xenios-ag.com
www.xenios-ag.com

CEO Dr. Andreas Terpin
CMO/COO Jürgen O. Böhm, MD

Supervisory Board
Dr. Olaf Schermeier,
(Chairman)
Christof Köster
Stefan Trappe

Registered Office
Heilbronn
County Court Stuttgart
HRB 743620

UST.Id.-Nr. DE266481056
St.-Nr. 65200/97008

Kreissparkasse Heilbronn
Konto 304 232
BLZ 620 500 00
IBAN
DE48 6205 0000 0000 3042 32
SWIFT
HEISDE66

Please note:

- The products can be returned to us by means of pick-up or return shipment at our expense.
- You will of course receive a credit note for the returned products once we have received them.

Please ensure that all parties concerned within your organisation or other affected organisations are informed of this Field Safety Notice.

Please confirm that you received this Field Safety Notice by completing and returning the enclosed reply form to the following address via mail or email. Please contact us also if you have further questions about this Field Safety Notice and/or the specified measure.

Contact: Xenios AG
Nina Altschäffel
Complaint Manager
Im Zukunftspark 1
74076 Heilbronn
Germany
Email: fsn@Xenios-ag.com

We apologise for the inconvenience caused and thank you for your cooperation!

Heilbronn, 07.06.2019

Name Dr. Andreas Terpin
Position CEO

Name Dr. Jürgen Böhm
Position CMO/COO

Name Thomas Junesch
Position Safety Officer

Name Alexander Becker
Position Head of Product and Therapy Management

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Feedback form for Field Safety Notice deltastream DP3 pump head

Xenios AG
Nina Altschäffel
Complaint Manager
Im Zukunftspark 1
74076 Heilbronn
Germany
Email: fsn@Xenios-ag.com

Products concerned:

Product name	Article no.	Batch no.	Quantity of products in storage	Quantity of products already used	Quantity of products currently in use
Support.set Säuglinge, hilite 800 LT, rheoparin beschichtet, Modell Medos	MEH2C4024 (30000074)	190104M354			

We do hereby confirm that the safety and corrective actions have been passed on to all relevant departments and that the Field Safety Notice has been read, understood and implemented.

We confirm that we/our customers do not have any further products of the above mentioned batches on stock.

Company name: _____

Department: _____

Responsible person: _____

_____/_____
City Date Signature

We prefer the following option for return of goods:

- ☐ Pick-up
☐ Return shipment

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