

Medos Medizintechnik AG . Obere Steinfurt 8 - 10 . 52222 Stolberg, Germany

Contact person:

Fax: +49 7131 2706-299
E-Mail: FSN@xenios-ag.com

Heilbronn, 21. Mai 2021

Important safety note

FSN21-02: Due to the increased complaints rate (trend) of pump head recently, Medos Medizintechnik AG recognized a potential risk of the product and thus decided to recall following products from the market.

Affected Products: Tubing set for the organ perfusion

Brand names	Liver Assist-Set, Model Organ Assist	Organ Perfusionset, Kidney net, Model Organ Assist
Reference number	MEH133411	MEH132909
Affected batch number	190220M146	190403M954
Quantity	18	48

Date: 21. May 2021

Reference number: FSN 21-02

Addressee: [REDACTED]

Reason: This letter means to inform you about the deficiency of the products. The products with above mentioned batch number include defective pump head and this could cause malfunction of the tubing set.

Dear Mr. [REDACTED]

Due to the increased complaints regarding pump head DP2, the company Xenios recognize a potential risk of the product. The results of the complaints investigation shows the pump head was glued together and thus a non-rotating pump head.

Description of the product deficiency

The described pumphead problem is caused by deficiencies during the production phase.

Measures of recall on affected products

- Please assure that the customer return the products immediately.
- Please check your stock for the appropriate products or batches.
- Complete the enclosed feedback form and send it either by fax to: +49 7131 2706-299, in electronic form by e-mail to fsn@xenios-ag.com or by mail to Medos Medizintechnik AG, Safety Officer, Subject: FSN 21-02, Im Zukunftspark 1, 74076 Heilbronn, Germany.
- Return all remaining stocks of this product immediately.

Products may be returned to Medos Medizintechnik AG as follows: by pickup or by your own return shipment at Xenios AG's expense.

- Regarding crediting of affected products, please contact Customer Service: customerservice@xenios-ag.com, +49 7131 2706-100

Passing on this safety notice:

This notice and the resulting actions must be followed for an appropriate period of time to ensure the success of the actions.

Contact:

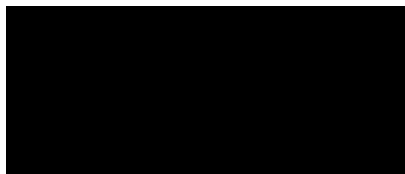
For questions regarding the attached feedback form, please contact us by e-mail at fsn@xenios-ag.com.

A copy of this urgent safety notice has been sent to the Federal Institute for Drugs and Medical Devices, as the coordinating authority, to inform them of the proposed action.

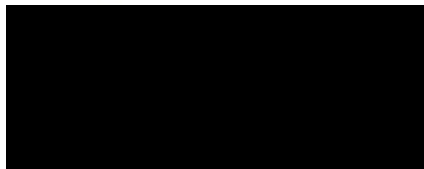
We hereby expressly apologize for any inconvenience caused and thank you for your cooperation!

Heilbronn, 21. Mai 2021

Name
Position



Medos Medizintechnik AG



Medos Medizintechnik AG

Urgent Safety Notice Feedback Form

FSN21-02: Due to the increased complaints rate (trend) of pump head recently, Medos Medizintechnik AG recognized a potential risk of the product and thus decided to recall following products from the market.

Medos Medizintechnik AG
- Safety Officer
Im Zukunftspark 1
74076 Heilbronn
Deutschland
Fax : +49 7131 2706-299
Email: fsn@Xenios-ag.com

Distributor Data

Distribututor Details	
Name of the distributor	
Adress	
Contact Name	

Affected products Liver Assist-Set, Model Organ Assist

Product Name	Reference number
Liver Assist-Set, Model Organ Assist	MEH133411

Affected Lots

Lot-Number	Quantity of available products	Quantity of used products	Quantity of returned products	Quantity of disposed products
190220M146				

Affected products Organ Perfusionset, Kidney net, Model Organ Assist

Product Name	Reference number
Organ Perfusionset, Kidney net, Model Organ Assist	MEH132909

Affected Lots

Lot-Number	Quantity of available products	Quantity of used products	Quantity of returned products	Quantity of disposed products
190403M954				

Communication with authorities

Please list all countries where the affected products were distributed by you:

	select an applicable answer.	
<input type="checkbox"/>	I confirm that I have notified the competent authorities where I have distributed the products	Date of communication:
<input type="checkbox"/>	I confirm that in the countries the notification to the competent authorities has been made	Date of communication:
<input type="checkbox"/>	There is no communication with the relevant authorities from our side.	

Implementation of the measure by Organ Assist

select all applicable answers

<input type="checkbox"/>	I confirm that I have received, read and understood the safety notice	
<input type="checkbox"/>	I have checked my inventory and put in affected products into restricted stock	Date of execution and quantity of separated products
<input type="checkbox"/>	I have identified all customers who have received or may have received this device	
<input type="checkbox"/>	I have informed the identified customers about this measure	Date of communication:
<input type="checkbox"/>	I have received a response confirmation from all identified customers	
<input type="checkbox"/>	Neither I nor any of my customers have an affected product in inventory	
Name		
Signature		
Date		