

medos AG . Im Zukunftspark 1 . 74076 Heilbronn. Germany

Contact:

To whom it may concern

Fax: +49 7131 2706-299

E-Mail: fsn@xenios-ag.com

Heilbronn, 08. Okt 2020

Field Action: "FSN20-02"

Dear valued distributor,

Medos AG has introduced a new Cleaning-, disinfection- and storage- instruction for Novatherm / DeltastreamHC. Please assure that in future only the new procedure is used at your customers institutions.

1. Information on Affected Devices	
a) Device Type(s)	Heater Cooler Devices
b) Commercial name(s)	Novatherm / Deltastream HC
c) Unique Device Identifier(s) (UDI-DI)	N/A
d) Device Model/Catalogue/part number(s)	MEDPHC0001, MEDPHC0002, 4000122, 4000127, 5000100, 5000101, 30000144
e) Software version	N/A
f) Affected serial or lot number range	All
g) Associated devices	Within context of the FSCA: All



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2. Reason for Field Safety Corrective Action (FSCA)	
a) Description of the product problem	No product problem. This FSCA is intended to distribute a new cleaning-, disinfection- and storage- instruction.
b) Hazard giving rise to the FSCA	An inaccurately cleaned device might become contaminated with germs such as mycobacteria.
c) Probability of problem arising	Depends on the accuracy of cleaning the device
d) Predicted risk to patient/users	Potential infection
e) Further information to help characterize the problem	None
f) Background on issue	Medos had received reports that devices were contaminated with mycobacteria
g) Other information relevant to FSCA	N/A



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3. Type of Action to mitigate the risk	
a) Action To Be Taken by the User <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Provide further details of the action(s) identified.	
b) Actions to be completed by:	6 months
c) Is customer reply required? (If yes, form attached specifying deadline for return)	Yes
d) Deadline (if needed)	
e) Action Being Taken by the Manufacturer <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
f) Until when should the action be completed?	6 months
g) Is the FSN required to be communicated to the patient or user?	Yes
h) If yes, has manufacturer provided additional information suitable for the patient or user in a patient or non-professional user information letter?	
Yes Appended to this FSN	





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4. General Information	
a) FSN Type	New
b) For updated FSN, reference number and date of previous FSN	N/A
c) For Updated FSN, key new information as follows:	
N/A	
d) Further advice or information already expected in follow-up FSN?	No
e) If follow-up FSN expected, what is the further advice expected to relate to:	
N/A	
f) Anticipated timescale for follow-up FSN	None
g) Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
a. Company Name	See letter-head
b. Address	See letter-head
c. Website address	See letter-head
h) List of attachments/appendices:	IFU Addendum
i) Name/Signature	 XENIOS AG
	
	Insert Name and Title here and signature below
j) FSN Type	New
k) For updated FSN, reference number and date of previous FSN	N/A



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Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Please report this to the national Competent Authority if appropriate, or report us if that is not done by your organization.



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Distributor/Importer Reply Form for Field Action: "Nummer einfügen"

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN20-02
FSN Date	08. Okt 2020
Product/ Device name	Medos Heater Cooler devices
Product Code(s)	
Batch/Serial Number (s)	

2. Distributor/Importer Details	
Company Name	
Account Number	
Address	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	fsn@xenios-ag.com
Deadline for returning the Distributor/Importer reply form	2 weeks

4. Competent Authority report acknowledgement to Sender		
The products have been distributed from us to the countries:	Please List all Countries where the affected products have been distributed:	
Please select one.		
<input type="checkbox"/>	I confirm having reported to the competent authorities where I have distributed the products	Date of communication:
<input type="checkbox"/>	I confirm in the countries the reporting to the competent authorities was done	Date of communication:
<input type="checkbox"/>	No competent authorities communication will be done from our side	



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5. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name		
Signature		
Date		

Mandatory fields are marked with

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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