medos AG . Im Zukunftspark 1 . 74076 Heilbronn. Germany

Contact:

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

To whom it may concern

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

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

Xenios AG
Im Zukunftspark 1
74076 Heilbronn, Germany

T +49 7131 2706 0
F +49 7131 2706 299

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. DE286481056
St.-Nr. 65200/97008

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

3. Type of Action to mitigate the risk

a) **Action To Be Taken by the User**

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☒ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ 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**

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☒ IFU or labelling change
☐ Other ☐ 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

Xenios AG
Im Zukunftspark 1
74076 Heilbronn, Germany

T +49 7131 2706 0
F +49 7131 2706 299

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. DE286481056
St.-Nr. 65200/97008

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

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	[redacted] XENIOS AG
		[redacted]
		Insert Name and Title here and signature below
	j) FSN Type k) For updated FSN, reference number and date of previous FSN	New
		N/A

Xenios AG
Im Zukunftspark 1
74076 Heilbronn, Germany

T +49 7131 2706 0
F +49 7131 2706 299

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. DE286481056
St.-Nr. 65200/97008

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

	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.**

Xenios AG
Im Zukunftspark 1
74076 Heilbronn, Germany

T +49 7131 2706 0
F +49 7131 2706 299

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. DE286481056
St.-Nr. 65200/97008

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

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.	
☐	I confirm having reported to the competent authorities where I have distributed the products	Date of communication:
☐	I confirm in the countries the reporting to the competent authorities was done	Date of communication:
☐	No competent authorities communication will be done from our side	

Xenios AG
Im Zukunftspark 1
74076 Heilbronn, Germany

T +49 7131 2706 0
F +49 7131 2706 299

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. DE286481056
St.-Nr. 65200/97008

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

5. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	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
☐	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
☐	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.

Xenios AG
Im Zukunftspark 1
74076 Heilbronn, Germany

T +49 7131 2706 0
F +49 7131 2706 299

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. DE286481056
St.-Nr. 65200/97008

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