Reproline medical GmbH , Zeissstrasse 15 , 53359 Rheinbach

February 12th, 2023

CUSTOMER ADDRESS

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urgent safety information
PRODUCT RECALL
CONCERNING
SOFT DENUDATION TIPS AND FOLLICLE PUNCTION SYSTEMS

Dear Ladies and Gentlemen,

This letter is to inform you that we are conducting a voluntary product recall of the following products.
Please ensure that all users and necessary persons are informed of this urgent safety information.

Medical devices concerned:

Article	LOT	Prod. – Date	EXP - Date
Soft Denudation Tips	44200203	2020-04	2023-04
	44200303	2020-07	2023-07
	44200403	2020-10	2023-10
	44210103	2021-01	2024-01
	44210203	2021-04	2024-04
	44210303	2021-07	2024-07
	44210403	2021-10	2024-10
	44220103	2022-01	2025-01
	44220203	2022-04	2025-04
	44220303	2022-07	2025-07
	44220403	2022-10	2025-10
	44230103	2023-01	2026-01
Follicle puncture Systems	46200201	2020-04	2023-04
	46200301	2020-07	2023-07

Article	LOT	Prod. – Date	EXP - Date
Follicle puncture Systems	46200401	2020-10	2023-10
	46210101	2021-01	2024-01
	46210201	2021-04	2024-04
	46210301	2021-07	2024-07
	46210401	2021-10	2024-10
	46220101	2022-01	2025-01
	46220201	2022-04	2025-04
	46220301	2022-07	2025-07
	46220401	2022-10	2025-10
	46230101	2023-01	2026-01
	48200201	2020-04	2023-04
	48200301	2020-07	2023-07
	48200401	2020-10	2023-10
	48210101	2021-01	2024-01
	48210201	2021-04	2024-04
	48210301	2021-07	2024-07
	48210401	2021-10	2024-10
	48220101	2022-01	2025-01
	48220201	2022-04	2025-04
	48220301	2022-07	2025-07
	48220401	2022-10	2025-10
	71200201	2020-04	2023-04
	71200301	2020-07	2023-07
	71200401	2020-10	2023-10
	71210101	2021-01	2024-01
	71210201	2021-04	2024-04
	71210301	2021-07	2024-07
	71210401	2021-10	2024-10
	71220101	2022-01	2025-01
	71220201	2022-04	2025-04
	71220301	2022-07	2025-07
	71220401	2022-10	2025-10
	72200201	2020-04	2023-04
	72200301	2020-07	2023-07
	72200401	2020-10	2023-10
	72210101	2021-01	2024-01
	72210201	2021-04	2024-04
	72210301	2021-07	2024-07
	72210401	2021-10	2024-10
	72220101	2022-01	2025-01
	72220201	2022-04	2025-04
	72220301	2022-07	2025-07
	72220401	2022-10	2025-10
	73200201	2020-04	2023-04
	73200301	2020-07	2023-07
	73210201	2021-04	2024-04

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KölnBonn / Swift-Code COLSDE33XXXVolksbank
IBAN DE96 3706 9627 0035 4330 15
Voreifel / Swift-Code GENODED1RBCKreisissparkasse
IBAN DE38 3705 0299 0045 8438 69

Bonn Rhein-Sieg / Swift-Code GENODED1BRS
DE56 3705 0198 0005 4049 26IBAN DE38 3806 0186 0706 9230
Köln / Swift-Code COKSDE33XXX

Article	LOT	Prod. – Date	EXP - Date
Follicle puncture Systems	73210301	2021-07	2024-07
	73220101	2022-01	2025-01
	73220201	2022-04	2025-04
	73220401	2022-10	2025-10
	73230101	2023-01	2026-01
	79200201	2020-04	2023-04
	79200301	2020-07	2023-07
	79200401	2020-10	2023-10
	79210101	2021-01	2024-01
	79210201	2021-04	2024-04
	79210301	2021-07	2024-07
	79210401	2021-10	2024-10
	79220101	2022-01	2025-01
	79220201	2022-04	2025-04
	79220301	2022-07	2025-07
	79220401	2022-10	2025-10
	93200201	2020-04	2023-04
	93200301	2020-07	2023-07
	93200401	2020-10	2023-10
	93210101	2021-01	2024-01
	93210201	2021-04	2024-04
	93210301	2021-07	2024-07
	93210401	2021-10	2024-10
	93220101	2022-01	2025-01
	93220201	2022-04	2025-04
	93220301	2022-07	2025-07
	93220401	2022-10	2025-10

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Reasons for this recall:

In the past, there was a systematic error in the release process of the products. At present, the safety of the products with regard to embryotoxicity in particular cannot be demonstrably confirmed for all batches produced.

Health risk:

In the course of the risk assessment, the present situation was evaluated. The embryotoxicity that may be present could cause harm to embryos and oocytes. Therefore, customers are requested to return or destroy the products.
Do not continue to use the products. We ask you to check your stock to see if you have one or more products. **Please return them to us or destroy them and send us one or more meaningful photos clearly showing the number of affected LOT numbers you have destroyed.**

Once your inventory is complete, please sign and return the enclosed "Recall Confirmation and Return Form". This confirms that you have received the recall notification and that you intend to comply with it.
Please return the form within 24 hours.

We are very sorry for the inconvenience caused to you, please be assured that we are working to resolve the matter fully.

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CONFIRMATION AND RETURN FORM FOR THE RECALL
SOFT DENUDATION TIPS & FOLLICLE PUNCTURE SYSTEMS

CUSTOMER ADRESS

I have read and understood the information given in the letter of 12.02.2023.
Recall instruction read and understood ☐

exclusively to distributors:

I have my customers to whom these products were supplied identified and notified. (Attach attachment, including date and type of notification) ☐

TABLE WITH INFORMATION ON THE PRODUCTS CONCERNED

ART-No.	LOT	Delivered on	Delivered QTY	QTY destroyed

Reproline medical GmbH
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12
Tel.: +49(0)2226-9005-0
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IBAN DE38 3705 0299 0045 8438 69

FIELD FOR REPLY:
Please provide additional information if applicable.

Name / Title

Telephone number

Email address

Please send the completed reply by e-mail or FAX to:

e-mail: recall@reproline-ivf.de
Fax number: +49(0)2226/900555

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CONTACT INFORMATION

If you have any questions, please contact

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With kind regards
Reproline medical GmbH

Ludger Hoppe
-Managing Director-