REPROLIFE
2-5-3-9F, Shinjuku, Shinjuku-ku, Tokyo, Japan 160-0022 tel. +81-3-5925-8931

FSN Ref. FSN_REPROLIFE_07Oct2022 FSCA Ref. No. R22-024

Date: 2022-10-07

Urgent Field Safety Notice

Product Name/Trade name:

Tissue Storage Plates, 10Vitri Plate and 10Warm Plate

For Attention of: ALL CUSTOMERS

Contact details of local representative
Swiss Authorized Representative: DECOMPLIX AG Freiburgstrasse 3 CH-3010 Bern CHRN-AR-20001403 Contact person: Mrs. Helena Lacalle E-mail: vigilance@decomplix.com Phone: +41 32 365 33 33 **Swiss Importer:** NMS BIOMEDICAL SA Chésalles 15 CH-1723 Marly CHRN-IM-20000125 Contact person: Mr. Nemeshazy Janos Istvan E-mail: nms.bm@bluewn.ch Phone: +41 26 413 01 50

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Field Safety Notice (FSN)
Tissue Storage Plates, 10 Vitri Plate and 10 Warm Plate
Missing paper IFU

Description of the issue:

REPROLIFE's Tissue Storage Plates were released without the accompanying Instructions for Use (IFU) in paper form. The IFUs were provided only electronically, via web site, as e-IFU.

All serial numbers released prior to 05 August 2022 are concerned.

Risk might arise from this issue:

Some users, health care professionals, may not see the e-IFUs because of poor or lack of Internet access. It may cause mistakes in operation.

These devices do not contact patients and hazard to patients themselves cannot happen but oocytes, embryos and tissues etc. from patients may be damaged or wasted by incorrect use of the devices. Also, REPROLIFE considers that there is no residual risk after implementation of the corrective action in this FSN, provided all users handling the devices follow the IFUs properly.

Corrective Action to be taken by the Manufacture:

- ➔ REPROLIFE has started releasing Tissue Storage Plates with paper IFUs from 05 August 2022.
- ➔ REPROLIFE is providing all customers who already purchased and received the products beforehand with the paper IFUs in the mandatory local language(s).
- ➔ REPROLIFE is requesting the affected customers to sign the attached IFU receipt and send it back to REPROLIFE.

Action to be taken by the Customer:

- ➔Fill out the attached FSN receipt and send it back to REPROLIFE via email to takeda.k@reprolife.jp, **by 21 October 2022**
- ➔ Deliver the IFUs in paper form that REPROLIFE is providing you to all your customers to whom you have provided the affected devices and maintain proof thereof.
    - If your customer is not the end user of the affected devices, ensure this FSN is transferred to your customer for action and maintain proof thereof.

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Action to be taken by the End User (Healthcare Professional):

➔Fill out the attached FSN receipt and send it back to REPROLIFE via email to takeda.k@reprolife.jp, **no later than 21 October 2022**

Sincerely,

Shin Tanaka.

Shin Tanaka
Director of Quality Assurance Department
REPROLIFE Inc.

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FSN Receipt

For Distributing Agent

To: REPROLIFE Inc., at **takeda.k@reprolife.jp**

Date of shipment to distributor	Product name	Number of packs	Order number	Lot number

I have received IFUs in the same number (××) as the number of plate product packs shown above, and have sent IFUs in the same number as the number of sold packs to our customers of those plate products, as indicated below.

I confirm I maintain proof of the delivery/provision of paper IFUs to our customer.

Date when the paper IFU was provided	IFU reference	Number of IFU units	Name and address of customer/facility that has received the paper IFU	End User? (Y/N)

In cases where our customer was not the end user, I confirm I have passed the present FSN to such customers for action.

Name of agent: _____

Person in charge: _____

Signature: _____

Date of signature: _____

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FSN Receipt

For healthcare professionals/institute

To: REPROLIFE Inc., at **takeda.k@reprolife.jp**

Date of shipment	Product name	Number of packs	Order number	Lot number

I have received IFUs in the same number (××) as the number of plate product packs shown above.

Date of receipt: _____

Name of facility: _____

Person in charge: _____

Signature: _____