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

Urgent Field Safety Notice

FSCA reference No. : R22-024

Product Name/Trade name:
Tissue Storage Plate:10Vitri Plate, Tissue Storage Plate:10Warm Plate

30 September 2022,

Dear Customers,

We would like to inform you about the following issue with our products: Tissue Storage Plate: 10 Vitri Plate and Tissue Storage Plate: 10 Warm Plate and corrective action that have been performed and will be performed.

Description of the issue:

Tissue Storage Plates were released without the designated IFUs by the technical documentation. The IFUs designated were provided only by web site as e-label.

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 will not contact patients and hazard to patients themselves cannot be happened 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 the FSN action, in case where the all users handling the devices follow the IFUs properly.

Corrective Action to be taken by the manufacture:

- Have released Tissue Storage Plates with written IFUs from 05 Aug 2022
- Provide all customers who already purchased and received the products beforehand with the written IFUs in each their local language
- Request the customers to sign the attached receipt and send it back to REPROLIFE

Action to be taken by the customer:

- Please see the IFUs in paper form that RPROLIFE sent and distribute them to the healthcare professionals those who have used the products.
- Please fill the attached receipt out and send it back to REPROLIFE via email by 21 Oct 2022

Sincerely,

Signature

Shin Tanaka
Director of Quality Assurance Department
REPROLIFE Inc.

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Ref No. R22-024

Receipt

For Distributing Agent

To: REPROLIFE Inc.

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, and have sent IFUs in the same number as the number of sold packs to our customer facilities of those plate products.

<Name of facility receiving IFUs>

_____

_____

_____

_____

_____

_____

_____

Name of agent: _____

Person in charge: _____

Signature: _____

Date of signature: _____

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Ref No. R22-024

Receipt

For healthcare professionals/institute

To: REPROLIFE Inc.

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: _____