Updated March 29,2018

 **By Electronic Mail**

March 28, 2018

Lars Vinther

Mermaid Medical

Frydensbergvej 25

DK-3660 Stenloese

Denmark

**Urgent Regulatory Field Action Notice**

**Commercial name of affected products :** RANFAC Bone MARROW BIOPSY NEEDLE (RBN), Ranfac Aspiration Needle (RAN), Galactography Infusion Unit (GIU), Ranfac Bone Marrow Biopsy Needle (RTN)

**FSCA :-**Ranfac-001

**Type of action:** Medical Device return to Supplier / Medical Device Destruction

Attention Lars Vinther,

**Details on affected devices:**

The product listed in the attached Confirmation Form, and the subject of our “Notice to Distributors” date March 14, 2018 now needs to be returned or scrapped.

**Reason for request:**

This field action notice comes due to the expiration of the Product Quality Assurance certificate number CE 01760. The identified products were imported into the EU after the expiration of this certificate. Ranfac has completed an assessment and there is no inherent impact to product safety or performance.

**Advise on action to be taken by users:**

It is requested that the following actions be taken:

* All product must be identified and quarantined
* All quarantined product and product identified as already used must be documented and communicated to bzimble@ranfac.com.
* Please complete the attached Confirmation Form (Attachment 1) to identify the quantity and location of these devices..
* Based upon the information provided regarding the identification, quantity and location of the identified product, Ranfac will decide if the product should be scrapped or returned.
* Disposal instructions will be provided by Ranfac upon receipt of product identification communication and will include instructions to either scrap the product or will include shipping and RMA information.

**Transmission of this Field Action Notice:**

Mermaid Medical has indicated that these identified devices have been further distributed to other distributors or end users, as indicated in your email of March 24, 2018. It is requested that this Field Action Notice be provided to all other relevant organizations as soon as possible and before Wednesday, April 2, 2018. These organizations are requested to take the same actions as outlined above.

**Please confirm that this notification has been provided to these relevant organizations.**

**It is further requested that these organizations notify Ranfac of all product that has been used by a patient for traceability.**

**Contact reference person:**

Barry H. Zimble

Ranfac Corp.

30 Doherty Ave.

Avon, MA 02322

USA

(508) 588-4400

**The undersign confirms that the appropriate Regulatory Agencies have been advised of this notice.**

Thank you for your prompt cooperation in this matter.

Sincerely,

Barry H. Zimble

Barry H. Zimble

Executive Vice President & General Manager

Cc: Emergo Europe – vigilance@emergogroup.com

**Attachment**

**CONFIRMATION FORM**

**Please indicate on this form the location of the devices, quantity of the devices at each location, and confirmation that this Field Action Notice has been provided.**

**Instructions:**

* Please indicate the all locations of the identified lot numbers in the column identified as “Location”.
* Please indicate the total quantity of devices sent to each identified location in the column identified as “Quantity”.
* Please indicated Yes (Y) or No (N) in the “Notification Provided” column to indicate if this notification has been provided to the other relevant organizations identified in the below spreadsheet.

| Catalog | Part# | Total qty Shipped after 1/21/18 | Lot #’s | Manufacture date | Location | Quantity | Notification Provided  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| RBN-114S | 74092-01M | 287 BOXES | LOT 38605 | 1/9/2018 |  |  |  |
|  RBN-114S |  74092-01M | 13 BOXES | LOT 39000 | 1/3/2018 |  |  |  |
| RBN-114S | 74092-01M | 300 BOXES | LOT 39293 | 2/12/2018 |  |  |  |
| RBN-116 | 74049-02M | 12 BOXES | LOT 38399 | 10/2/2017 |  |  |  |
| RBN-133 | 74050-03M | 12 BOXES | LOT 38004 | 8/31/2017 |  |  |  |
| RBN-84 | 74224-01M | 237 BOXES | LOT 38521 | 1/15/2018 |  |  |  |
| RBN-84 | 74224-01M | 136 BOXES | LOT 39103 | 2/7/2018 |  |  |  |
| RTN-84 | 74211-01M | 14 BOXES | LOT 38755 | 1/2/2018 |  |  |  |
| RTN-84 | 74211-01M | 10 BOXES | LOT 39169 | 1/18/18/ |  |  |  |
| RTN-84 | 74211-01M | 60 BOXES | LOT 39168 | 1/26/2018 |  |  |  |
| RAN-15-M | 74060-03M | 140 BOXES | LOT 38505 | 12/29/2017 |  |  |  |
| RAN-15-M | 74060-03M | 120 BOXES | LOT 39072 | 1/26/2018 |  |  |  |
| RAN-154-M | 74060-04M | 82 BOXES | LOT 38509 | 12/21/2017 |  |  |  |
| RAN-154-M | 74060-04M | 72 BOXES | LOT 39078 | 1/26/2018 |  |  |  |
| GIU-31 | 68008-06M | 5 BOXES | LOT 37646 | 6/26/2017 |  |  |  |

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**Mermaid Medical \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Please email back to** **bzimble@ranfac.com**

**Thank you,**

Barry H. Zimble

Executive Vice President & General Manager