SEBBIN PARIS

ESTHETIQUE & RECONSTRUCTION

**Danish Medicines Agency**
**Axel Heides Gade 1**
**DK – 2300 KOBENHAVN**

Boissy l'Aillerie, February 8, 2018

**Subject : Recall of medical devices manufactured by INEX and distributed by GROUPE SEBBIN**

File : n°CA 18-01-001-RA

**URGENT – FIELD SAFETY NOTICE**

GROUPE SEBBIN distributes the medical devices manufactured by the company INEX.
These medical devices must bear the EC marking.
However, we were informed that the EC certificate n°MED 070080 of the sterile medical devices, class IIa, issued by the notified body EZU #1014, to the company INEX was not renewed.
The expiration date was November 29, 2017.

We did not receive any reliable evidence of the renewal of the EC certification for the devices; consequently, even though INEX certified to us that there were no safety risks for the patients and users, we decided to withdraw the distributed devices from the market since November 29, 2017.
You will find enclosed the letter supplied by INEX.

Please note that the devices returned to GROUPE SEBBIN will be sent back to INEX by GROUPE SEBBIN.
For your information, the distribution of the medical devices manufactured by INEX will resume as soon as a valid EC certificate will be issued by their notified body.



www.sebbin.com

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TVA intracommunautaire N°FR 94 519 665 467. SAS au capital de 2 665 790 euros. RCS 519 665 467. Siret 519 665 467 000 14

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The local distributor or the Sebbin subsidiary have been identified as having received the incriminated products by GROUPE SEBBIN.
The letter sent to the distributor or Sebbin subsidiary is attached for your information.

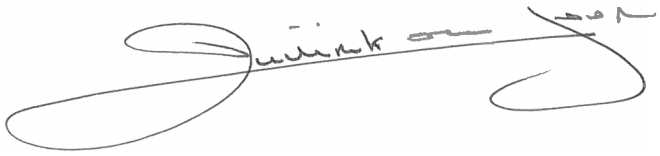
This safety information must be sent to the end users by the local distributors (excepted for the French direct sales). To follow all products placed on the market, we need the help of the local distributor and subsidiary in completing the table.

For your information, the French competent authority (ANSM) has been notified of this safety corrective action.

We are at your disposal for any further information.

We do apologize for this inconvenience caused by this event.

Sincerely yours,



**Diederik VAN GOOR**
Quality & Regulatory Affairs Director



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