

# Urgent Field Safety Notice

Commercial name of the affected product: ZAMST Filmista Ankle  
FSCA-identifier (e.g. date) : 2018-07-25  
Type of action (e.g. chapter 4 definition of a FSCA): CORRECTIVE ACTION

Date: July 25, 2018

Attention: Ms. Xavière Curtenaz

### Details on affected devices:

Model name: ZAMST Filmista Ankle  
Item number: 470201, 470202, 470203, 470204, 470211, 470212, 470213 and 470214  
Shipped from Euro Trading from September 2017 through June 2018

### Description of the problem:

An inaccuracy in the labelling; Specifically, omission of numerical values on the sizing chart on the packaging was found.  
Lack of the information may interfere the customers in selecting an appropriate sizing. Therefore, Nippon Sigmamax Co., Ltd. has decided to take corrective action on already distributed products.



### Advise on action to be taken by the distributors:

1. Announce all distributors to check their inventory, how many Filmista Ankle with the WRONG package they have by the end of August 2018.
2. The standard operation procedures and the draft of work completion report will be released by Nippon Sigmamax Co., Ltd. by the end of August 2018 in order to explain how to put a correction sticker on each packaging of applicable lot.
3. Nippon Sigmamax Co., Ltd. will send necessary quantity of the correction stickers to you. Then you will distribute the stickers to the distributors who have the Filmista Ankle with the WRONG packages immediately.
4. The distributors will send the work completion report back to the manufacturer by the middle of October 2018.

**Contact reference person:**

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The undersign confirms that this notice has been notified the appropriate Regulatory Agency

(Closing paragraph)

Signature