

Dear Sir,

As a precaution, we would like to inform you that TEKNIMED SAS has decided to proceed to a voluntary withdrawal of the following mentioned products. We invite you to carefully read the present notification and to take the below mentioned measures.

**Affected device:**

Product description	Product reference	Batch number	UDI number
EuroscREW Ø9 L30	T720930	7220076	03760177040397

**Description of the situation:**

In the pouch, the screw is not a Standard EuroscREW but a EuroscREW NG (different designs: screw pitch, screwdriver footprint).

**Potential related risks:**

An evaluation of the risks related to this non-conformity has been performed and **concluded to the absence of risk for the patient**, because it will be impossible to put the screw on the screwdriver.

The only identified risk is an impossibility to use the screw with the Standard EuroscREW screwdriver because of a non-adapted footprint.

**Actions to be taken by customers and users:**

To avoid any issue, we therefore kindly request you to take the following actions:

- Notify this withdrawal to all the persons concerned in your facility and to your customers,
- Isolate the concerned products in your facilities and/or in your customers' ones.
- Complete and return by e-mail, **as soon as possible or at the latest by March 10th**, the attached statement for the products destruction, by indicating the concerned quantity to TEKNIMED SAS, Quality Department [quality@teknimed.com](mailto:quality@teknimed.com)
- Destroy the entire batch 7220076 that you have in stock and send us the proof of the destruction (picture).

**Contact information:**

Our vigilance correspondent and Quality Manager, Franck DRUILHET, remains at your disposal for any further assistance or information at the following phone number : +33 5 34 25 10 60.

If you need to receive this notification in the official language of your country, please let us know so that we can put the necessary measures in place.

We are sincerely sorry for the inconvenience caused and we will do our best to provide you compliant units as soon as possible.

Yours faithfully,

**Clémentine DEMONT**

*Ingénieure Assurance Qualité / Quality Assurance Engineer*

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