

**Urgent Field Safety Notice**  
**Voluntary recall**

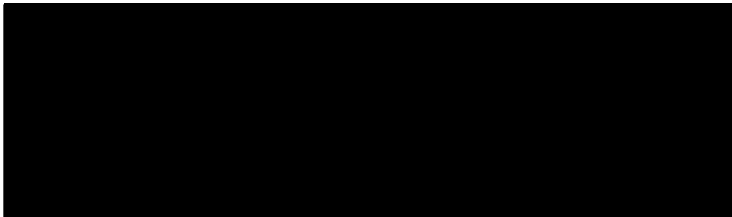
**ELISIO-19H**

**FSCA 2016/03/24**

**Type of action : Return of a Medical Device to the supplier**

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Date: 24/03/2016



**Details on affected devices:**

**Product name:** ELISIO-19H

**Product code:** ELI-19H-GC

**List of lot numbers involved:** 15I06AHA

**Total number of units involved:** 8016 units

**Description of the problem:**

On February 8<sup>th</sup>, Nipro Medical Hefei received a complaint regarding the expiry dates mentioned on the dialyzers of lot 15I06AHA of the ELI-19H-GC were not consistent. The correct expiry date is 2018-08, but for some of the dialyzers the expiry date 2015-08 is shown. This is due to a printing mistake. All the products of this lot have been produced on September 6<sup>th</sup> 2015 as indicated on the label and therefore cannot be expired on August 2015. The real expiry date is 2018-08 for all goods of this lot.

However, to avoid confusion Nipro decided to recall the concerned goods.

**Advise on action to be taken by the user:**

Please put the goods from this lot number separately and do not further distribute or use them.

Our Quality department will contact you very soon with instructions on how to return the goods.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

**Contact reference person:**

Ann Vankrunkelsven  
Nipro Europe NV



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1930 Zaventem  
Belgium

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

