SFRI
Medical Diagnostics
Valuing Life, Value for Life

Recall Letter rRef. SFRI_RL-GM_20220511

Date May 9th, 2022.

Product

Product description	Reference	Lot number	US/EU UDI
IonoRef solution for IONIX device calibration	**IO1SOL01**	**134701**	**n/a**

Object Product recall of IonoRef solution from lot number 134701 (quantity: 201 units) due to a contamination of the solution (NC 319 2022/02).

Effect on the results of patient analyse

- The results of patient analyse could be delayed due to the difficulty to get a fine calibration.
- There is no direct impact on the conformity of the results for the patient analyses when the calibration has been succeed and the controls are compliant to the specifications.
  Refer to IonoRef leaflet.

Actions for the Client

- Discontinue use and destroy any IonoRef solution remaining in your inventory of lot number 134701 in accordance with your laboratory procedures.
- Please fill out the Customer Response Form and return it.
- Contact Order Services immediately if you do not have a replacement lot.
- If you have distributed the above product to other laboratories, please inform them of this product recall letter and forward a copy to them.
- Please retain this letter for your documentation.

Contact

- If you or the healthcare professionals with whom you work have any questions regarding this information, please contact SFRI Assistance at +33 5 56 68 80 50.
- If you are aware of any patients or users impacted by the information in this product recall letter, please contact Customer Service immediately.

Date : 2022-05-09

SFRI
SAS au capital de 75 000 €
N° 453 866 824 RCS Bordeaux
Lieu-dit "Berganton"
33127 Saint Jean d'Illac - France
TVA : FR 38 453 866 824
Tél. : +33 (0)5 56 68 80 50 – Fax : +33 (0)5 56 21 79 03

Gilles MOUGIN
Gérant de NEOVITEA,
Présidente de SFRI

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Document à retourner par mail à l'adresse assistance@sfri.com

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UDI Product	Product Name	Product reference	Batch number	Expiry date
n/a	IonoRef solution	IO1SOL01	134701	2023-05

CUSTOMER INFORMATION

Name of the laboratory:	
Name of the person responsible for signing:	
Mailing adress:	
Phone number /Email :	
Customer code number:	

DECLARATION

☐ I did not received this batch number.

☐ I have read the information relating to this Safety Advisory regarding the product referenced above, and I have proceeded in accordance with the instructions.

Quantity of affected units received:		Quantity of affected units destroyed according to the instructions of the product leaflet:	
If the quantity of units destroyed is different from the quantity received, please indicate this quantity:			

Date: Signature and Laboratory stamp: