

Urgent Field Safety Notice

Voluntary recall of specific lot numbers of Vacumed® BLOOD COLLECTION SET

NIPRO CORPORATION

Product code: Vacumed BLOOD COLLECTION SET

Lot numbers: 18F22; 18F25; 18F25; 18G13; 18G19; 19B12; 19B13

FSCA 2019/11/28

Type of Action: Voluntary Recall of lot numbers for Vacumed BLOOD COLLECTION SET

Dear Sir or Madam,

The purpose of this communication is to inform you that NIPRO CORPORATION is voluntarily initiating Field Safety Corrective Action 2019/11/28 on a specific lot number of the below medical device:

- Vacumed BLOOD COLLECTION SET

Details of the affected devices:

Product Name	Quantity affected	Product Lot No.
RBC HARD 21GX3/4 (190LA) ISO FL	120,000	18F22
RBC HARD 21GX3/4 (190LA) ISO FL	80,000	18F25
RBC HARD 23GX3/4 (190LA) ISO FL	120,000	18F27
RBC HARD 21GX3/4 (190LA) ISO FL	100,000	18G13
RBC HARD 21GX3/4 (190LA) ISO FL	50,000	18G19
RBC HARD 21GX3/4 (190LA) ISO FL	100,000	19B12
RBC HARD 21GX3/4 (190LA) ISO FL	50,000	19B13

Description of the problem:

At Nipro Corporation, we have a continuous commitment to patient safety and routinely monitor the performance of our products to ensure that we meet customer expectations.

According to our internal investigation, Nipro Corporation has identified that the products bearing product code Vacumed BLOOD COLLECTION SET were not listed appropriately in the technical documentation.



Root cause analysis:

Based on the analysis of the actual complaint samples, retention samples, and simulation study – it has been observed that no safety risk is involved in products themselves

Corrective and preventive action:

Nipro Corporation has taken an immediate corrective action after the discovering of the error of documentation to correct it. And already released a Declaration of Conformity in order to ensure compliance and safety of this product.

Advice on action to be taken by the user:

Please put the goods from these lot numbers separately and do not further distribute or use them. Please send the goods from the affected lot numbers back Nipro Italy.

Transmission of this Field Safety Notice:

This notice should be distributed to the Nurse Manager / Head Nurse of each affected facility. Please complete and return the FSN Response Form to Rossella Sindona – Complaint Manager, Nipro Medical Europe rossella.sindona@nipro-group.com **within 10 working days** so we are assured that you have received and distributed this important communication.

Contact reference person:

The undersigned: Rossella Sindona, Complaint Manager, Nipro Medical Europe

Rossella Sindona

Complaint Manager

