Interster International
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Subject: Urgent Field Safety Notice

FSCA 11-08-2017

Return of the Medical Device to the manufacturer

Date Issued: 11th August 2017, 14:00 P.M, GMT (Greenwich Mean Time)

Audience

Hospital and clinic administrators, purchasing departments, distributors, pharmaceutical offices.

Product

Sterisets Medical Products product reference "3FSET130630" and description "Spuit 50 ml per 20 stuks verpakt" is a medical device component kit set which contains empty 3 piece luer lock syringes with tip cap, intended for the preparation and administration of medical substances or pharmaceutical solutions.

Purpose

To alert health care professionals and facilities to stop using batch number 1705019 manufactured during May 2017 due to a still yet non identified foreign matter.

The affected batch information is as follows:

REF	Product name	Batch	Qty (in pieces)
3FSET130630	Spuit 50 ml per 20 stuks verpakt	1705019	1.000

Summary of problem and scope

Sterisets Medical Products is a contract manufacturer of medical devices used in Hospitals and Clinics, we produce several procedure custom kit sets with the outmost care and concern regarding quality in our products. We received a complaint stating that our product distributed by Interster International appeared to have two non-conformities:

- Syringes deformed
- Some syringes appeared to have a brownish substance

After analysis of the media in the form of pictures, which were sent together with the complaint form, it was possible to observe all the non-conformities with a sufficient degree of certainty that allowed the Quality Department of Sterisets to provide an initial conclusion on the problem.

The physical aspect of the syringes although is considered a deformation it would not impact the characteristics of the performance of the product and therefore is not a reportable incident to the authorities.

The brownish unidentified substance due to the intended use of the syringes can lead to unanticipated adverse reactions or unanticipated side effects causing injury to patients, therefore the decision was made to recall the product.

Advice on action to be taken by the user

The products have been manufactured by Sterisets Medical Products and sold to Interster International only.

Sterisets Medical Products is responsible to initiate the return of the products (recall) and therefore requires the products to be placed in quarantine.

Interster International assures that the products will be in quarantine at Interster facilities, this includes all products which have still not been used and are distributed to his customers.

Forward-Looking Statements

Sterisets Medical Products expect to release forward-looking statements of our investigation that are based on hard evidence from our laboratory testing results that will allow us to conclude on this issue.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within Interster International organization and to other organizations on which this action has an impact (Interster customers).

The Dutch Healthcare Inspectorate will be advised of this FSCA.

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Contact manufacturer

Sterisets Medical Products

Att.: Mrs. Isabel Nascimento – QAM

Dr. João Quirino - Pharmacist

Address:

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Portugal

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Acknowledgment of receipt

Sterisets International B.V./Sterisets Medical Products, requires an acknowledgment of receipt of this notice.

With regards,

Sterisets International B.V./Sterisets Medical Products

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