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Field Safety Notice

regarding occasional quality defects when using the products ELS 65 ml syringe and syringe sets (ELS) of MEDTRON AG

Corrective measure: Recall

Receiver: user, operating company, distributor

Concerned medical devices:

MR-Set ELS 65ml
ELS 65ml syringe

Identification of concerned medical devices:

MR-Set ELS 65ml REF 317602-000, LOT 20190724
ELS 65ml syringe REF 316065-000, LOT 20190716

Description of the problem including the identified cause:

We have been informed by our supplier of the above-mentioned ELS syringes and syringe sets that the mentioned batches may possibly contain particles inside the syringes.

In order to avoid any danger for patients, we recall the batches concerned.

After having consulted the supplier, we can definitely limit the potential defect to the mentioned batches.

Measures to be taken by the user:

We have to point out to you that the batches concerned must not be used any more. Please return the enclosed "*Acknowledgement of receipt of product recall R-2020-01*" to the specified email address until **February 21th 2020**.

If you still have any unused products of the batches concerned, please return them to your distributor or to MEDTRON AG so that we can replace the products or credit the purchase price to your account.

Forwarding the information described in this letter:

Please make sure that all users of the above-mentioned products in your company and other persons to be informed take note of this "**Field Safety Notice**". If you have passed the products to third parties, please forward a copy of this information or inform the contact person mentioned below.

Please keep this information at least until the measure has been completed, i.e. until the products of the mentioned batches are no longer in use.

The "Bundesinstitut für Arzneimittel und Medizinprodukte" (German Federal Institute for Drugs and Medical Devices) has received a copy of this "Field Safety Notice".

Contact person:

Manuel Warth

Sicherheitsbeauftragter nach § 30 Medizinproduktegesetz (MPG)

Tel.: +49 681 97017 41

E-Mail: m.warth@medtron.com

If you have any further questions, please do not hesitate to contact us.

Mit freundlichen Grüßen

MEDTRON AG



i.V. Manuel Warth

Sicherheitsbeauftragter nach § 30 Medizinproduktegesetz (MPG)

Acknowledgement of receipt of product recall R-2020-01

Please fill in this form and return it immediately per email to

m.warth@medtron.com

- We hereby confirm that we have been informed about the product recall of 2020-02-13 regarding the above-mentioned article and batch numbers. The product recall has been communicated within our organisation.

References concerned	Batch number	Quantity delivered	Quantity identified in stock and put in quarantine	Quantity distributed/ Sold (only for distributors)	Quantity recovered from your customers (only for distributors)	Quantity used by your customers
			<i>(to be returned to MEDTRON)</i>		<i>(to be returned to MEDTRON)</i>	
317602-000	20190724					
316065-000	20190716					

Name: _____

Telephone/fax number: _____

Date/signature: _____

Stamp: