VAN OOSTVEEN MEDICAL B.V.
MEDICAL DISPOSABLES

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

Urgent Field Safety Notice

Romed 2-part syringes, 20 ml, reference number: SYR-20ML
FSCA 30 December 2016
Revision 1

Date: *05 January 2017*

Attention: *All European distributors and end-users of the Romed 2-part 20ml Syringes, batch numbers 150608, 154015, 151204 and 160202.*

Details on affected devices:

Affected products are the Romed 2-part 20ml syringes from four different batch numbers, produced in 2015 and 2016.

REF: SYR-20ML	LOT: 150608
	LOT: 151015
	LOT: 151204
	LOT: 160202

Description of the problem:

In a number of our Romed 2-part 20 ml syringes, a brown matter was detected which was identified as remainder of the injection moulding manufacturing process. Although not considered directly harmful, the presence of this material is not according to EN ISO 7886-1:1997 (Sterile hypodermic syringes for single use. Syringes for manual use), and can cause confusion with users. No adverse event has been reported for this issue at this time. Van Oostveen Medical B.V. is actively working on implementing corrective and preventive actions regarding this issue.

Advise on action to be taken by the user:

Distributors and end-users who make use of the Romed 2-part 20 ml syringes are requested to review their inventory for the affected lot numbers. Affected products in stock are requested to be blocked for use immediately. Distribution of affected products has to be discontinued. All affected products can be returned to your distributor for replacement.

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.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Frank van Kuijk, MSc
qualitycontrol@romed.nl

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