



Urgent Field Safety Notice

Rite Aid Hydrogel Breast Discs 12pk

Lot No. 15C22

FSCA Ref No. HD12_15C22_NET072401

Return of medical device to supplier or device destruction

Date: 15 July 2024

Attention: ////////////////

Details on affected devices:

Brand: Rite Aid

Product: Hydrogel Breast Discs 12pk

Lot No.: 15C22

Description of the problem:

The Rite Aid Hydrogel Breast Discs 12pk with Lot No. 15C22 was supplied to the Netherlands in error without appropriate CE marking. As such, the labelling is non-compliant with the MDR (EU) 2017/745.

Advise on action to be taken by the user:

- Identify and quarantine the products with Lot No. 15C22
- **For Users:**
 - Complete a confirmation form and submit to: info@borstvoeding.com
 - Return the products to the following address:
Borstvoeding.com
Palmpolstraat 70
1327 CH Almere, Netherlands
or
 - Dispose of the products according to state or local government requirements
- **For the Distributor:**
 - Complete a confirmation form and submit to: marketing@tolife.com.au
 - Return the products to the following address:
ToLife Technologies Pty Ltd
53 Banksia Road, Welshpool
Western Australia 6106
or
 - Dispose of the products according to state or local government requirements

TOLIFE TECHNOLOGIES PTY LTD

53 Banksia Road
Welshpool
Western Australia 6106

PO Box 36
Welshpool
Western Australia 6106

T: +61 8 9350 5688
F: +61 8 9350 5988
E: marketing@tolife.com.au



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:

Joseph Carpio
ToLife Technologies Pty Ltd
53 Banksia Road, Welshpool,
Western Australia 6106
+61 8 9350 5688
marketing@tolife.com.au

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

Signature

Joseph Carpio
ToLife Technologies Pty Ltd

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Field Safety Notice Confirmation Form

Product Name: Rite Aid Hydrogel Breast Discs 12pk

Lot No.: 15C22

Name of Person Completing the Form:			
Organisation Name (if applicable):			
Phone Number:		Email Address:	

By completing and signing this form, I confirm that I have read and understood the information included in the Field Safety Notice. I have taken the following actions.

Quantity of Affected Items on Hand (in units):			
Action Taken:	<input type="checkbox"/> Disposal	<input type="checkbox"/> Return to Supplier	

IF DISPOSED

Quantity Disposed (in units):		Date of Disposal:	
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IF RETURNED TO SUPPLIER

Quantity Disposed (in units):		Date of Disposal:	
Tracking (if applicable):			

Other Comments:	
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Signature:

Date:

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