

FSN Ref: 20022

FSCA Ref: N/A

Date: 22:01:2021

Field Safety Notice
Clinell Universal Wipes and Spray

For Attention of*:All users of Clinell Universal Wipes and spray in all healthcare settings


Contact details of local representative (name, e-mail, telephone, address etc.)*

**Gama Healthcare Ltd, Regulatory Department, 2 Regal way, Watford,
Hertfordshire, WD24 4YJ, UK - regulatory@gamahealthcare.com –
02079930030**

As of 01/03/2021, New Address:

**The Maylands Building,
Maylands Avenue, Hemel Hempstead Industrial Estate,
Hemel Hempstead, Hertfordshire, HP2 7TG**

Field Safety Notice (FSN)
Clinell Universal Wipes and Spray
Updated labelling

1. Information on Affected Devices*	
1	<p>1. Device Type(s)*</p> <p>Clinell Universal Wipes are non-sterile wipes and spray for the surface disinfection and cleaning of non-invasive medical devices.</p> 
1	2. Commercial name(s)
.	Clinell Universal Wipes and spray
1	3. Unique Device Identifier(s) (UDI-DI)
.	5060130440119, 5060130443851, 5060130448870, 5060130440782, 5060130448894, 5060130444629, 5060130446913, 5060130447231, 5060130445183, 5060130440300, 5060130448917, 5060130448948, 5060130440638, 5060130448986, 5060130440225, 5060130448955, 5060130440522, 5060130440003, 5060130445749
1	4. Primary clinical purpose of device(s)*
.	Surface disinfection and cleaning of non-invasive medical devices.
1	5. Device Model/Catalogue/part number(s)*
.	CW200, CWAB50, CWAB50SEU, CWCP50, CWCP50SEU, CW100, CW100EU, CWF360E, CWF160, CWTUB100, CWTUB100SEU, CWTUB100MENA, CWTUB100R, CWTUB100R2, CWBUC225, CWBUC225SEU, CWBUC225R, CDS500, CDS750
1	6. Software version
.	N/A
1	7. Affected serial or lot number range
.	N/A
1	8. Associated devices
.	N/A

2 Reason for Field Safety Notice	
2	1. Description of the product problem*
.	IFU & label update
2	2. Hazard giving rise to the FSN*
.	The product contains various known sensitisers, giving rise to a risk of allergic reaction upon contact with skin. By use of gloves and appropriate PPE, though very low likelihood, any potential hazards are minimised. The updated cautions make this clearer. Other possible misuses are also identified on the cautions.
2	3. Probability of problem arising
.	Very low likelihood of occurrence: less than 1 in 200 million (0.0000005%) based on adverse event reports
2	4. Predicted risk to patient/users
.	Very low likelihood of occurrence. Less than 1 in 200 million (Any type of reaction). Less than 1 in 5 billion (Type 1 reaction)
2	5. Further information to help characterise the problem
.	The same biocidal formulation used for Clinell Universal Wipes is also used in Clinell Antimicrobial Hand Wipes with no reported reactions in nine years.
2	6. Background on Issue
.	<p>In mid-2020, Gama Healthcare completed their Notified Body transition from Intertek (0473) to NSAI (0050). During the transition and update of Notified Body on the labelling, the opportunity was also taken to update the cautions section of the packaging. The update includes clarifying statements on use, potential risks and foreseeable misuse. The clarification highlights that these are wipes intended for use in cleaning and disinfecting medical devices.</p> <p>There have been no changes to the Clinell Universal Wipes other than the labelling. The new labelling will be coming onto the market as the previous stock is exhausted.</p>
2	7. Other information relevant to FSN
.	<p>The IFU and caution wording is changing as follows (relevant new wording in bold underlined):</p> <p><u>Clinell Universal Wipes</u> are intended for the disinfection and cleaning of non-invasive medical devices. The wipes are for single use by healthcare professionals in all healthcare settings. <u>CAUTION: Not for personal use. Avoid using wipe to clean skin. Avoid contact with eyes & mucous membranes. Use gloves & appropriate PPE. Direct contact with skin may cause allergic reactions.</u> Discontinue use if irritation develops. If irritation persists for more than 72 hours, seek medical advice. Do not use on complex or invasive medical devices. Always follow medical device manufacturer's cleaning & disinfecting guidelines. Keep out of the reach of children. Do not use if package is damaged. Do not use if wipe is dry. Do not use the wipes in combination with other disinfectants. Clinell Universal Wipes have not been tested on all non-enveloped viruses.</p>

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>
3.	<p>2. By when should the action be completed?</p> <p style="text-align: center;">N/A</p>
3.	<p>3. Particular considerations for:</p> <p style="text-align: center;">N/A</p> <p>Is follow-up of patients or review of patients' previous results recommended? N/A</p>
3.	<p>4. Is customer Reply Required? *</p> <p>(Please respond to cover email to confirm receipt and dissemination of this notice)</p> <p style="text-align: right;">Yes</p>
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>
3	<p>6. By when should the action be completed?</p> <p style="text-align: center;">31st of March 2021</p>
3.	<p>7. Is the FSN required to be communicated to the patient /lay user?</p> <p style="text-align: right;">No</p>
3	<p>8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</p> <p style="text-align: center;">N/A</p>

4. General Information*	
4.	1. FSN Type* New
4.	2. For updated FSN, reference number and date of previous FSN N/A
4.	3. For Updated FSN, key new information as follows: N/A
4.	4. Further advice or information already expected in follow-up FSN? * No
4	5. If follow-up FSN expected, what is the further advice expected to relate to: N/A
4	6. Anticipated timescale for follow-up FSN N/A
4.	7. Manufacturer information
	a. Company Name GAMA Healthcare Ltd.
	b. Address 2 Regal Way, Watford, Hertfordshire, WD24 4YJ, UK. As of 01/03/2021, New Address: The Maylands Building, Maylands Avenue, Hemel Hempstead Industrial Estate, Hemel Hempstead, Hertfordshire, HP2 7TG
	c. Website address www.gamahealthcare.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes
4.	9. List of attachments/appendices: None
4.	10. Name/Signature Graham Milward Deputy RA & QA Director

Transmission of this Field Safety Notice	
	<p>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. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.