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FSN Ref: CSN-FSN-2026-1
FSCA Ref: CSN-FSCA-2026-1
MMA FSCA ref no. FSCA054-2026

Date: 12/06/2026

Urgent Field Safety Notice

Aquaflush Trans anal irrigation system
Initial notification

For Attention of*:Importers and distributors in EU

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

Country	Customers Name	Email	Address	Telephone
Ireland	Pat Coakley	alison@patcoakleymedical.ie	PAT COAKLEY MEDICAL LTD UNITS E3 & E4 NETWORK ENTERPRISE PARK KILCOOLE CO. WICKLOW IRELAND A63 H244	+353868536748
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Germany	Clinisupplies Deutschland GmbH (Importer)	frank.altmeyer@clinisupplies.com	120a Dahlweg Münster	+49 (0)251 149849-02

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Urgent Field Safety Notice (FSN)

Aquaflush Trans anal irrigation system

Risk addressed by FSN

1.	**Information on Affected Devices***
	1. Device Type(s)*
	Aquaflush Trans anal irrigation system. This is a non-sterile, non-measuring, Class I device. s supplied with a lubricant gel provided in a separate foil pouch as an ancillary item Refer to the attached appendix 1 for impacted SKUs list, UDI codes, product codes device name and trade name.
	2. Commercial name(s)
	Aquaflush Trans anal irrigation system
	3. Unique Device Identifier(s) (UDI-DI)
	Refer to the appendix 1
	4. Primary clinical purpose of device(s)*
	The device is intended to be used specifically for trans-anal irrigation of the bowel in adult and paediatric patients with functional bowel disorders such as chronic constipation and LARS or for patients with neurological bowel dysfunction.
	5. Device Model/Catalogue/part number(s)*
	Refer to appendix 1
	6. Software version
	Not applicable
	7. Affected serial or lot number range
	All the lot numbers available in EU market are impacted
	8. Associated devices
	Not applicable

2.	**Reason for Field Safety Corrective Action (FSCA)***
	1. Description of the product problem*
	We have temporarily suspended the supply of the Aquaflush Tran Anal Irrigation system to the EU market. No new batches will be shipped until further notice. We are communicating with all EU importers and distributors to initiate recall of the affected products currently on the market. Distributors will communicate directly with end users to provide clear instructions on returning/destroying the unused product. The device is currently classified as a Class I medical device and is supplied with a lubricant gel provided in a separate foil pouch as an ancillary item. The Authority has indicated that, as the lubricant gel is intended for use within body orifices, it should be classified as a Class IIb

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device under Regulation (EU) 2017/745. Consequently, this impacts the overall classification of the system, indicating that the product has not been classified appropriately to date.

We acknowledge the Authority's regulatory interpretation and confirm our commitment to complying with the revised classification requirements.

2. Hazard giving rise to the FSCA*

The FSCA has been initiated due to a regulatory non-compliance related to the classification of the device under Regulation (EU) 2017/745 (EU MDR). The product has not been classified and placed on the market in full alignment with the applicable MDR classification requirements.

As a result, there is a possibility that customers may have received and used a device that is not fully compliant with current EU regulatory provisions.

The situation presents a **low-level risk**, limited to the possibility of users having access to a device that does not fully meet current MDR regulatory classification requirements. No specific hazards leading to harm have been identified

3. Probability of problem arising

Negligible

The probability of the issue arising is considered low.

- The issue relates to the regulatory classification status of the device rather than its design, manufacture, or functionality.
- There is no triggering event or failure mode that would cause the problem to manifest during normal use.
- The likelihood is therefore limited to situations where a device is placed on the market or used without full compliance with MDR classification requirements.

Based on currently available information, including post-market data, the occurrence of any impact to users or patients is considered unlikely, and the issue is confined to a compliance gap rather than an operational or clinical failure.

4. Predicted risk to patient/users

The predicted risk to patients and users is considered low, but not absent.

Although the issue is related to regulatory non-compliance rather than a device defect, the following potential risks have been identified:

Patients may be treated using a device that does not fully meet current EU MDR regulatory requirements, which represents a compliance-related risk rather than a direct clinical hazard.

5. Further information to help characterise the problem

Not any

6. Background on Issue

We refer to the Competent Authority's (MMA) recent observation regarding the classification of the Aquaflush Trans Anal Irrigation (TAI) System. The device is currently classified as a Class I medical device and is supplied with a lubricant gel provided in a separate foil pouch as an ancillary item. The Authority has indicated that, as the lubricant gel is intended for use within body orifices, it should be classified as a Class IIb device under Regulation (EU) 2017/745. Consequently, this impacts the overall classification of the system, indicating that the product has not been classified appropriately to date. This change

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	necessitates assessment by a notified body and, in its current state, may result in non-compliant devices being placed on the European market. We acknowledge the Authority's regulatory interpretation and confirm our commitment to complying with the revised classification requirements. This will include updating the technical documentation, undergoing the appropriate conformity assessment procedures, and engaging a notified body as required.
	7. Other information relevant to FSCA
	Not any

3.	**3. Type of Action to mitigate the risk***	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☒ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Any unused device must be returned, and any used device must be destroyed	
3.	2. By when should the action be completed?	25/06/2026
3.	3. Particular considerations for: NA Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Not a implantable device, no follow up required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	

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	The manufacturer will communicate with all EU importers and distributors to initiate recall of the affected products currently on the market. They will be instructed to communicate with customers/end users for returning of the unused quantities of the product.		
3	6. By when should the action be completed?	25/06/2026	
3.	7. Is the FSN required to be communicated to the patient /lay user?		Yes
3	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?		
	Yes Not appended to this FSN		

	4. General Information*	
.	1. FSN Type*	New
.	2. For updated FSN, reference number and date of previous FSN	Not applicable
.	**3.** For Updated FSN, key new information as follows:	
	Not applicable	
.	4. Further advice or information already expected in follow-up FSN? *	No
	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
	6. Anticipated timescale for follow-up FSN	Not applicable
.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	1. Company Name	Clinisupplies (Nanjing) Co., Ltd.
	2. Address	No. 86-8 Shuanggao Road, Gaochun District Nanjing 211316 Jiangsu P.R. China
	3. Website address	www.clinisupplies.co.uk
.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	

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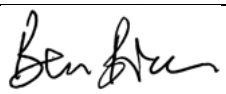
.	9. List of attachments/appendices:	**Appendices 1: Product details**
.	10. Name/Signature	**Ben Bian, General Manager, Clinisupplies (Nanjing)**
		

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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..*

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

Appendix 1. Product details

Product Group	Bowel management
Brand Name	Aquaflush Transanal Irrigation System
Generic Name	Transanal Irrigation System
GMDN Code/ Term	45510 – Manual rectal irrigation system
EMDN Code /terms	U0799 – Devices for the treatment of incontinence - other

Product Codes	**Device details (Size and Description)**	**UDI –** DI Codes (GTIN Codes)	
Aqua flush Actif	Device Details	Each	Shipper
AFAS	Aquaflush Actif starter set; Washbag, Waterbag & Pump, extension tube, 5 Cones	05060458870063	05060458870308

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AFAM	Aquaflush Actif monthly set; Waterbag & Pump, 15 Cones	05060458870056	05060458870292
Aqua flush Lite	Device Details	Each	Shipper
AFLS	Aquaflush Lite stater set; Washbag, **Waterbag & Pump, 7 Cones**	05060458870131	05060458870353
AFLM	Aquaflush Lite monthly set; Waterbag & Pump, 16 Cones	05060458870148	05060458870360
Aquaflush Self-Retaining Catheter (SRC)	Device Details	Each	Shipper
AFSRCM	Aquaflush Self-retaining cone starter set; Washbag, Waterbag & Pump, 5 Cones	05060458870247	05060458870414
AFSRCS	Aquaflush Self-retaining cone monthly set; Waterbag & Pump, 15 Cones	05060458870230	05060458870407
Aqua flush Compact+	Device Details	Each	Shipper
AFCPS	Aquaflush Compact+ starter set; Washbag, Pump, Extension Tube, 5 Cones	05060458870209	05060458870339
AFCPM	Aquaflush Compact+ monthly set; Pump, Extension Tube, 15 Cones	05060458870216	05060458870346
Aquaflush Compact	Device Details	Each	Shipper
AFCS	Aquaflush Compact starter set; Washbag, Pump, Extension Tube, 5 Cones	05060458870087	05060458870087
AFCM	Aquaflush Compact monthly set; Pump, Extension Tube, 15 Cones	05060458870070	05060458870070
Aquaflush Accessories	Device Details	Each	Shipper
AFLA	Aquaflush standard cone refill pack; 15 Standard Cones	05060458870193	05060458870377
AFSC	Aquaflush short cone refill pack; 15 Short Cones	05060458870223	05060458870384
AFSRCA	Aquaflush Self-retaining cone refill pack; 15 SRC Cones	05060458870254	05060458870391
Aquaflush new generation	Device Details	Each	Shipper
AF2	Aquaflush200 Standard Set (30 irrigations)	05060458870902	05060458871008
AF2X	Aquaflush200X Standard Set (30 irrigations)	05060458870926	05060458871022
AF5X	Aquaflush500X Standard Set (30 irrigations)	05060458870964	05060458871060
AF5XSC	Aquaflush500X Short Cone Set (30 irrigations)	05060458870988	05060458871091

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AF5XSRC	Aquaflush500X SRC Set (30 irrigations)	05060458870971	05060458871077
SPAF2	Aquaflush200 Starter Set	05060458870896	05060458870995
SPAF2X	Aquaflush200X Starter Set	05060458870919	05060458871015
SPAF5X	Aquaflush500X Standard Starter Set	05060458870933	05060458871039
SPAF5XSC	Aquaflush500X Short Cone Starter Set	05060458870957	05060458871053
SPAF5XSRC	Aquaflush500X SRC Starter Set	05060458870940	05060458871046