URGENT FIELD SAFETY NOTICE (FSN)

VOLUNTARY FIELD SAFETY CORRECTIVE ACTION (FSCA) — MEDICAL DEVICE RECALL
Regulation (EU) 2017/745 (EU MDR)

Device Commercial Name: Warrior Lite Base Unit (Blood and Fluid Warmer)
FSN Reference: FSEU 2026-01 | **Date of Notice:** 11 November 2026 | **Target Geographic Market:** European Union (EU) Member States & EEA

For Attention of:

- Clinical / Biomedical Engineering (EBME) Teams
- Hospital Administrators & Medical Directors
- Operating Theatre & Anaesthesia Managers
- Emergency, Trauma & Resuscitation Departments
- Intensive Care Units (ICU) & Critical Care Leads
- Hospital Risk Managers & Patient Safety Officers
- Medical Device Vigilance / Safety Officers (MDSO)
- Procurement, Materials Management & Supplies

Contact Details of Local Representatives in EU:

1. AUTHORISED REPRESENTATIVE IN THE EU (EC REP):

- **Entity Name:** MedNet EC-REP IIb GmbH
- **Address:** Borkstrasse 10, 48163, Münster, Germany
- **Contact Person:** Marie Reinker
- **Telephone / Fax:** +49 151 40202515
- **Email Contact:** Marie.Reinker@mednet-ecrep.com

2. LOCAL EU IMPORTER / DISTRIBUTOR:

- **Company Name:** **TBD (Local Designated Distributor / Importer)**
- **Address:** **TBD**
- **Contact Person:** **TBD**
- **Telephone / Fax:** **TBD**
- **Logistics / Reply Email:** **TBD (Local Distributor / Support Channel)**

Note: The EC REP acts as the legal regulatory liaison with EU Competent Authorities. The local Distributor/Importer coordinates customer reply forms, RMA logistics, and replacement base units.

1. Information on Affected Devices

Item	EU FSN Template Required Field	Field Safety Notice Information
1.1	**Device Type(s)**	The Warrior Lite inline Blood and Fluid Warmer is used for warming blood, blood products and IV fluids in order to prevent hypothermia. The system can operate with MAINS power or with battery power (supplied non-sterile).
1.2	**Commercial name(s)**	Warrior Lite Base Unit
1.3	**Unique Device Identifier(s) (UDI-DI)**	07290016740103
1.4	**Primary clinical purpose of device(s)**	The Warrior Lite Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration. The Warrior Lite Blood and Fluid Warmer device is indicated for use in diseases and conditions which may lead to or have led to hypothermia.
1.5	**Device Model / Catalogue / part number(s)**	Model / Catalogue Number: QIF03-BUA1000
1.6	**Software version**	Not Applicable (The defect is strictly an internal mechanical shield assembly non-conformance)
1.7	**Affected serial or lot number range**	Global Affected Serial Number Range: BUL01187 - BUL01197 and BUL01445 - BUL03790. Total quantity of units distributed in the EU: 41 units Expected Operational Life: 5 Years.

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1.8	**Associated devices**	Warrior Lite Base Unit, Catalogue Number: QIF03-BUA1000 only. **PLEASE NOTE: Single-use disposable warming sets, batteries, mounting accessories, and chargers are NOT affected by this manufacturing defect.**

2. Reason for Field Safety Corrective Action (FSCA)

Item	EU FSN Template Required Field	Field Safety Notice Information
2.1	**Description of the product problem**	Quality in Flow received isolated field reports concerning localized thermal overheating of the Warrior Lite system during fluid warming. Following a technical root-cause investigation, Quality in Flow determined that an internal mechanical shield was incorrectly assembled on the Printed Circuit Board Assembly (PCBA) during manufacturing. Under harsh environmental vibrations or mechanical impacts, an incorrectly assembled shield may detach from the PCBA and cause an electrical short circuit across PCBA components.
2.2	**Hazard giving rise to the FSCA**	If an electrical short circuit occurs while the Warrior Lite Base Unit is actively operating, localized thermal overheating can result. This overheating can cause the disposable unit's Expanded Polypropylene (EPP) casing to soften, deform, and emit an evident strong electrical odor. **• Hazard to Patient: If the overheating condition is not detected by clinical staff, hot fluid or steam may breach the deformed casing and leak onto the patient, creating a risk of thermal skin burns.** **• Hazard to Clinical User: Potential risk of contact burn or vapor exposure during handling if the hazard mitigation protocol is not immediately followed.** **• Residual Risk with FSN Actions: Following the mandatory inventory inspection, physical shake test, quarantine, and patient disconnection protocol reduces the residual risk to negligible.**
2.3	**Probability of problem arising**	Probability: Low / Rare under standard clinical operating conditions. The likelihood increases if the base unit has been subjected to significant mechanical shock, drops, or severe transit vibration that dislodges the incorrectly secured internal shield.
2.4	**Predicted risk to patient/users**	Health Hazard Evaluation (HHE) Outcome: Moderate clinical severity (localized reversible thermal skin burns) with a low probability of occurrence. EU MDR Vigilance Classification: Categorized as an FSCA / Field Safety Notice regarding a potential device malfunction. Zero permanent injuries or life-threatening harms have occurred.
2.5	**Further information to help characterise the problem**	**Critical Safety Metrics (EU & Worldwide):** • Total Incident Reports / Complaints Received: Specific isolated field complaints logged globally regarding localized overheating. • Reported Adverse Events / Patient Injuries: Zero (0) patient injuries or adverse health events have been reported worldwide or in the European Union to date. • Action Rationale: Initiated voluntarily out of an abundance of caution and adhering to the precautionary principle to prevent any potential harm.
2.6	**Background on Issue**	Quality in Flow identified the issue through routine post-market surveillance and investigation of returned units displaying localized casing deformation. Manufacturing records confirmed that specific production batches experienced a mechanical shield tooling assembly deviation. Root cause corrective actions have already been implemented in production (enhanced mechanical retention and 100% inspection). Containment is strictly limited to the identified serial number batches.

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2.7	**Other information relevant to FSCA**	European Competent Authority Notification: The relevant Competent Authorities of EU Member States have been formally notified of this Field Safety Corrective Action in accordance with Article 89 of Regulation (EU) 2017/745 (EU MDR). National Competent Authority Reference Numbers: TBD (Pending assignment by Competent Authorities)

3. Type of Action to mitigate the risk

Item	EU FSN Template Required Field	Field Safety Notice Information
3.1	**Action To Be Taken by the User**	**[X] Identify Device [X] Quarantine Device [X] Return Device [ ] Destroy Device** **[X] On-site device modification/inspection (Mandatory Physical Shake Test)** **[X] Follow patient management recommendations (Immediate Clinical Hazard Mitigation Protocol)** [ ] Take note of amendment/reinforcement of Instructions For Use (IFU) [ ] Other [ ] None **MANDATORY ACTIONS REQUIRED BY USER / HEALTHCARE ORGANISATION:** 1. Locate & Verify Serial Numbers: Check all clinical departments (operating theatres, emergency departments, trauma bays, intensive care units), equipment libraries, and mobile trauma vehicles. Turn each Base Unit upside down, inspect the bottom rating label (refer to Appendix 3 Visual Identification Guide) and verify serial numbers against the affected range. 2. Perform Physical Shake Test: Hold each Warrior Lite Base Unit firmly at arm's length and gently shake. A distinct, easily audible metallic rattling sound indicates the presence of a loose internal shield. (A video demonstration is accessible via customer support channels: https://drive.google.com/file/d/12JuAEByMdBnwn7c4KzyXTOD3zNUgk857/view?usp=drive_link). 3. Quarantine Affected Units: Immediately remove from clinical use any base unit matching the affected serial numbers AND any unit exhibiting an internal rattle. Place in a secure quarantine area clearly marked 'RECALLED DEVICE — DO NOT USE'. 4. Immediate Clinical Mitigation Protocol: If casing deformation, vapor, or a strong electrical odor is detected during active patient fluid warming: (a) IMMEDIATELY disconnect fluid delivery tubing from the patient; (b) Disconnect the power source from the Base Unit; (c) Quarantine both Base Unit and disposable set for investigation. 5. Complete Customer Reply Form: Complete and return the attached Customer Reply Form (Appendix 1) within 10 business days. 6. Transfer of Notice: If affected devices were transferred to another hospital, clinic, or third-party organisation, forward this notice immediately.
3.2	**By when should the action be completed?**	Within Ten (10) Business Days of receipt of this notice.
3.3	**Particular considerations for patient follow-up or review of previous results**	Patient follow-up or retrospective clinical review is NOT recommended. The failure mode produces an immediate observable physical reaction (casing deformation/odor) during active operation; no latent adverse clinical effects occur after treatment, and zero patient injuries have been reported.

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3.4	**Is Customer Reply Required?**	Yes. Mandatory Customer Reply Form (Appendix 1) must be returned by all healthcare facilities, even if zero affected inventory is held. Note: Commercial distributors and importers must complete the dedicated Distributor/Importer Reply Form (Appendix 2).
3.5	**Action Being Taken by the Manufacturer**	**[X] Product Removal** **[X] On-site device modification/inspection** [ ] Software upgrade [ ] IFU or labelling change **[X] Other: Free factory repair or replacement of affected Warrior Lite Base Units.** [ ] None **Manufacturer Action Plan: Quality in Flow LTD will provide free factory repair or replacement for all affected Warrior Lite Base Units. Upon receipt of the completed Reply Form, Quality in Flow or its local designated distributor will issue Return Material Authorisation (RMA) documentation and pre-paid shipping waybills.** **Do not destroy any units.**
3.6	**By when should the manufacturer action be completed?**	The manufacturer recall and replacement program will be completed within six (6) months of notice issuance.
3.7	**Is the FSN required to be communicated to the patient / lay user?**	No. The Warrior Lite System is a professional-use medical device operated exclusively by qualified clinical healthcare personnel and emergency responders.
3.8	**If yes, has manufacturer provided additional lay information?**	Not Applicable (Professional clinical use only).

4. General Information

Item	EU FSN Template Required Field	Field Safety Notice Information
4.1	**FSN Type**	New
4.2	**For updated FSN, reference number and date of previous FSN**	Not Applicable (Initial FSN for European Union)
4.3	**For Updated FSN, key new information as follows:**	Not Applicable
4.4	**Further advice or information already expected in follow-up FSN?**	No
4.5	**If follow-up FSN expected, what is further advice expected to relate to:**	Not Applicable
4.6	**Anticipated timescale for follow-up FSN**	Not Applicable

Item	EU FSN Template Required Field	Field Safety Notice Information
4.7	**Manufacturer Information & Authorised Representative**	**A. MANUFACTURER (HEADQUARTERS):** • Company Name: Quality in Flow LTD • Address: 23 Ha-Yetsira St., Petah Tikva, 4951251, Israel • Website: www.qinflow.com • Technical & Regulatory Contact: support@qinflow.com **B. AUTHORISED REPRESENTATIVE IN THE EUROPEAN UNION (EC REP):** • Entity Name: MedNet EC-REP IIb GmbH • Address: Borkstrasse 10, 48163, Münster, Germany • Contact Person: Marie Reinker • Telephone / Fax: +49 151 40202515 • Email: Marie.Reinker@mednet-ecrep.com **C. DESIGNATED EU IMPORTER / DISTRIBUTOR:** • Company Name: **TBD** • Address: **TBD** • Contact Person: **TBD** • Telephone / Fax: **TBD** • Logistics / Form Return Email: **TBD**
4.8	**Regulatory Authority Notification**	The Competent (Regulatory) Authorities of the relevant European Union Member States have been informed about this Field Safety Corrective Action communication to customers under Regulation (EU) 2017/745 (EU MDR). **Adverse Incident Reporting: In accordance with EU vigilance guidelines, all device-related incidents or quality concerns should be reported directly to the manufacturer, local distributor/representative, and to the national Competent Authority of your Member State.**
4.9	**List of attachments / appendices:**	• Appendix 1: Field Safety Notice Customer Reply Form (Healthcare Facilities / End-Users) • Appendix 2: Field Safety Notice Distributor / Importer Reply Form (2018_fsn_dis_imp_en Template) • Appendix 3: Visual Device Identification & Shake Test Guide (Figure 1: Bottom Label & Serial Number Location) • Instructional Shake Test Video Reference: Accessible at https://drive.google.com/file/d/12JuAEByMdBnwn7c4KzyXTOD3zNUgk857/view?usp=drive_link).
4.10	**Name / Authorised Signature**	Name: Omer Pechter Title: Director of RA/QA Company: Quality in Flow LTD Signature: _____ Digitally signed by Omer Pechter Date: 13 November 2026

Transmission of this Field Safety Notice (Mandatory Distribution Notice)

• This notice needs to be passed on to 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 (e.g. regional hospital networks, private clinics, emergency services, ambulatory transport units).
• Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
• Adverse Incident Reporting: Please report all device-related incidents to the manufacturer, distributor, or local authorised representative (EC REP), and to the national Competent Authority of your EU Member State, as this provides important vigilance feedback.

Appendix 1: Field Safety Notice Customer Reply Form

URGENT MEDICAL DEVICE RECALL — REF: FSEU 2026-01 | WARRIOR LITE BASE UNIT

Mandatory Requirement: Please complete and return this form within Ten (10) Business Days of receipt via email to support@qinflow.com (or to the designated Importer / Distributor), EVEN IF YOU DO NOT HOLD ANY AFFECTED INVENTORY ON SITE. For your convenience, you can also use a **digital form** (https://form.jotform.com/263142030742445)

Healthcare Facility / Hospital Name:	_____
Department / Clinic / Unit:	_____
Facility Address & Country:	Street: _____ City / Postal Code: _____ Country: _____
Contact Person Name & Title:	Name: _____ Title: _____
Contact Telephone & Email:	Tel: _____ Email: _____
1. Inventory & Label Inspection:	[ ] All Warrior Lite Base Units inspected against affected serial list [ ] No Warrior Lite Base Units currently held in inventory
2. Physical Shake Test Conducted?:	[ ] YES — Physical shake test conducted on all units held [ ] NO [ ] Not Applicable (No units held)
3. Number of Affected Units Identified:	_____ Total units matching affected serial range / exhibiting internal rattle
4. Serial Numbers Quarantined:	Serial No(s): _____ _____
5. Transfer to Other Organisations:	[ ] Potentially affected devices were NOT transferred to any other site [ ] Devices WERE transferred — List organisation(s) notified: _____
Mandatory Customer Confirmation:	I confirm receipt and understanding of this Urgent Field Safety Notice (FSEU 2026-01). I have identified, isolated, and quarantined affected Warrior Lite Base Units as required, performed the physical shake test, and forwarded this notice to any sub-organisations where applicable. Authorised Signature: _____ Date: ____/____/2026 Printed Name & Role: _____

Appendix 2: Field Safety Notice Distributor / Importer Reply Form

Template for a Field Safety Notice Distributor/Importer Reply Form (2018_fsn_dis_imp_en)
Mandatory Requirement: It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Field Safety Notice (FSN) Information	Manufacturer Pre-filled Details
FSN Reference number	FSEU 2026-01
FSN Date	13 November 2026
Product / Device name	Warrior Lite Base Unit (Blood and Fluid Warmer)
Product Code(s)	Catalogue Number: QIF03-BUA1000 (UDI-DI: 07290016740103)
Batch / Serial Number(s)	BUL01187 - BUL01197 and BUL01445 - BUL03790

Distributor / Importer Details	To be completed by Distributor / Importer
Company Name	
Account Number	
Address	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

Return acknowledgement to Sender	Pre-filled by Manufacturer / Sender
Email	support@qinflow.com (or EC REP: Marie.Reinker@mednet-ecrep.com)
Distributor / Importer Helpline	
Postal Address	Quality in Flow LTD, 23 Ha-Yetsira St., Petah Tikva, 4951251, Israel (or EC REP: Borkstrasse 10, 48163, Münster, Germany)
Web Portal	www.qinflow.com
Deadline for returning reply form	Within Ten (10) Business Days of receipt of this FSN

Tick	Distributors / Importers (Tick all that apply)	Distributor / Importer Action Status
[ ]	**I confirm the receipt, the reading and understanding of the Field Safety Notice.**	Distributor/Importer to complete
[ ]	I have checked my stock and quarantined inventory	Enter quantity and date: Qty: _____ Date: __/__/2026
[ ]	I have identified customers that received or may have received this device	Customer list identified: [ ] YES [ ] NO
[ ]	I have attached customer list	Attached: [ ] YES [ ] N/A
[ ]	I have informed the identified customers of this FSN	Date of communication: Date: ____/____/2026
[ ]	I have received confirmation of reply from all identified customers	[ ] YES (100% received) [ ] Partially received (_____/_____)
[ ]	I have returned affected devices – enter number of devices returned and date complete.	Add Qty, Lot/Serial Number, Date: Qty: _____ S/N: _____ Date: __/__/2026
[ ]	Neither I nor any of my customers has any affected devices in inventory	Confirmed: [ ] YES
	Print Name:	Distributor/Importer print name here: _____
	Title / Function:	Title: _____
	Signature:	Sign Here: _____
	Date:	Date: ____/____/2026

Appendix 3: Visual Device Identification & Shake Test Guide

WARRIOR LITE BASE UNIT (MODEL: QIF03-BUA1000)

This visual guide provides healthcare professionals, biomedical engineering teams, and distributor personnel with step-by-step instructions to verify product labelling, identify affected serial numbers, and perform the physical rattle inspection test.

LABEL & SERIAL NUMBER LOCATION and Physical Shake Test Indicator:

1. Turn the Warrior Lite Base Unit upside down to view the product rating label on the bottom housing.
2. Verify the Label Location on the bottom housing (outlined/highlighted in Red).
3. Verify the Serial Number (S/N) location inside the label box (outlined/highlighted in Blue) against the affected serial numbers. Refer to Figure 1.
4. Hold the unit at arm's length and shake gently. A distinct, easily audible metallic rattling sound indicates the presence of a loose internal mechanical shield. Refer to a video demonstration in the following link, or copy and paste the following URL into your browser: https://drive.google.com/file/d/12JuAEByMdBnwn7c4KzyXTOD3zNUgk857/view?usp=drive_link).



Figure 1: Bottom Housing Label Location (Red Highlight) & Serial Number Location Box (Blue Highlight)