MEQU A/S
Fruebjergvej 3
2100 Copenhagen, Denmark
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www.MEQU.dk

FSN Ref: FSN 2026-01 v.2.0
FSCA Ref: FSCA 2026-01 v.2.0
Date: 25Jun2026

Urgent Field Safety Notice
Product recall - °M Warmer
(Does not impact USA)

Dear °MEQU Customers and Distribution Partners,

This updated Field Safety Notice extends the initial recall from March 31, 2026, to include additional °M Warmer production batches.

- Potentially affected products were manufactured from June 2023 to June 2024.
- °M Warmers manufactured after June 2024 have been subject to enhancement of production controls.

Out of an abundance of caution, MEQU A/S has initiated this voluntary recall.

This Field Safety Notice and attached Recall Reply Form outlines the following procedure to be followed by you:

1. Investigate if you have any affected products in stock.
2. Quarantine, and do not use any affected products.
3. Fill out the attached Recall Reply Form and send to your local °MEQU sales representative or MEQU A/S.
4. Await response from your local °MEQU Sales Representative or MEQU A/S to coordinate return and replacement of affected products.

For any further information or support concerning the information within this Field Safety Notice, please contact your local °MEQU Sales Representative or MEQU A/S.

Sincerely,

MEQU A/S

Contact details of MEQU A/S or local °MEQU Sales Representative
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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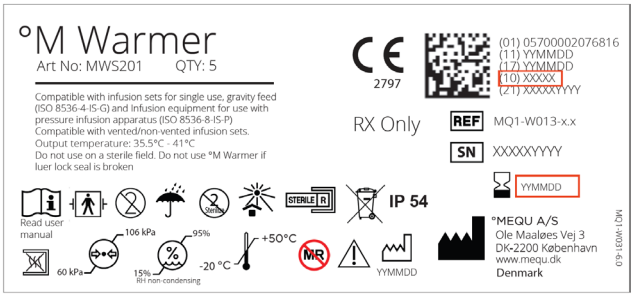
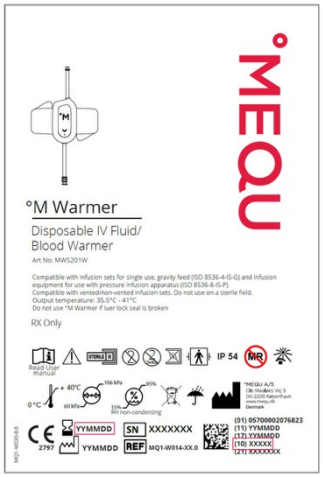
Urgent Field Safety Notice (FSN)
Product recall - °M Warmer
(USA not affected)

	1. Information on Affected Devices
1.	1. Device type
	The °M Warmer is a disposable IV-Fluid/Blood warmer and is part of the °M Warmer System.
1.	2. Commercial name
	°M Warmer
1.	3. Unique Device Identifier(s) (UDI-DI)
	05700002076823
1.	4. Primary clinical purpose of device
	°M Warmer is a disposable IV-Fluid/Blood warmer that is part of the °M Warmer System. The °M Warmer System is intended to warm blood, blood products and intravenous fluids prior to administration. It is designed to be used by healthcare professionals in pre-hospital, hospital, clinical and other environments to reduce the risk of hypothermia in the patient.
1.	5. Device Model/Catalogue/Part number(s)
	MWS201(Box of 5 °M Warmers) – Sales item MWS201W (Single °M Warmer in Silver Pouch) – Individual devices
1.	6. Affected serial or lot number range
	All affected °M Warmers can be identified by the following Expiry Dates (YYMMDD): 270620 + 270728 + 270907 + 271124 + 271213 + 280123 + 280206 + 280308 + 280322 + 280410 + 280419 + 280425 + 280513 + 280607 + 280612   Find expiry date next to hourglass symbol on MWS201 Box label or MWS201W Pouch label. Find LOT number in field number (10) next to QR code. For specific information on LOT numbers see overview in the attached LOT Number Overview.

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	2. Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	MEQU A/S has received reports of overheating of the °M Warmer. The investigation concluded that the failure occurred due to a misplaced sealing in the fluid path, causing an internal leak of fluids inside the °M Warmer, which may cause the °M Warmer to overheat. In case this happens, the °M Warmer's LED light turns flashing red, indicating that the safety circuit has been triggered due to overtemperature. In such a case immediately disconnect the °M Warmer from the power source and replace with a new °M Warmer. If undetected, the overheating may cause hot fluids to leak from the °M Warmer, potentially leading to harm.
2.	2. Hazard giving rise to the FSCA
	An incorrectly assembled sealing can cause a leak during use which may lead to overheating. The potential for harm is burns due to exposure to overheated device or fluid.

	3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☒ Other Please complete the enclosed Recall Reply Form. Please include contact details on the Recall Reply form.		
3.	2. By when should the action be completed?	Within sixty (60) business days of receipt of FSN	
3.	3. Is customer reply required? Recall Reply Form is attached specifying deadline for return.		Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ Product Removal Affected °M Warmer devices are being removed from the market and should be returned to MEQU A/S or your local °MEQU Sales Representative, incl. attached Recall Reply Form. All affected devices are manufactured from June 2023 to June 2024, prior to enhancements in production controls were implemented.		
3	5. By when should the action be completed?	Within 6 months from initiation of this Field Safety Notice	
3.	6. Is the FSN required to be communicated to the patient / lay user?		No

	4. General Information	
4.	1. FSN Type	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN 2026-01 Date: 31Mar2026
4.	3. For updated FSN, key new information as follows:	

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Date: 25Jun2026

	This update expands the initial recall of 4 production batches to include 11 additional production batches, all manufactured from June 2023 to June 2024.	
4.	4. Further advice or information already expected in follow-up FSN?	No
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	6. List of attachments:	1. Recall Reply Form 2. LOT Number Overview
4.	Name/Signature  Laila Lundtoft Chief RA/QA Officer, MEQU A/S	

	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