

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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(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 °M Warmer Art No: MWS201 QTY: 5 Compatible with infusion sets for single use, gravity feed (ISO 8536-4 IS-G) and infusion equipment for use with pressure infusion apparatus (ISO 8536-8 IS-P). Compatible with vented/non-vented infusion sets. Output temperature: 35.5°C – 41°C. Do not use on a sterile field. Do not use °M Warmer if luer lock seal is broken. Read user manual 100 kPa 60 kPa 15% RH non-condensing 95% +50°C 20°C IP 54 STERILE IP 54 YYMMDD CE 2797 RX Only REF MQ1-W013-x.x SN XXXXXXXX YYMMDD °MEQU A/S Ole Maaløes Vej 3 DK-2200 København www.mequ.dk Denmark 019-LE04-1204 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?	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:	

	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

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Field Safety Notice - °M Warmer **MWS201W / MWS201 Lot Number Overview**

The overview of expiry dates and LOT numbers below can be used to identify affected products. Products affected can be identified on the label of either the box of 5 °M Warmers (MWS201) or the individual °M Warmer (MWS201W).

Note - a °M Warmer is only affected if the label shows:

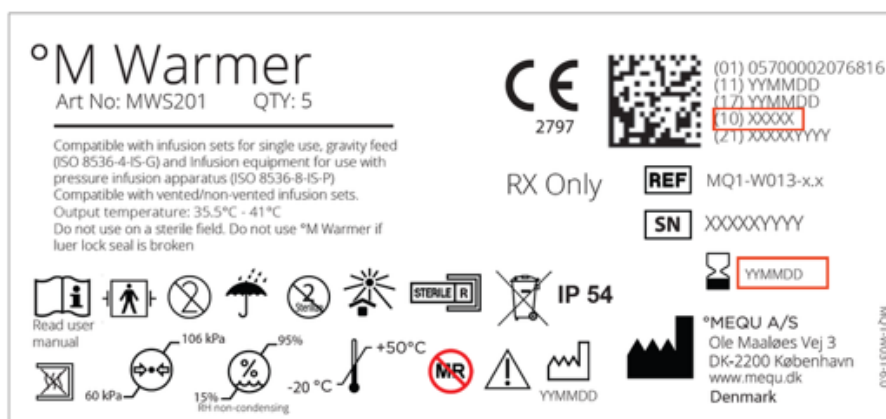
- Expiry date from list below

OR

- Expiry date and LOT number are both in the list below

Overview of affected boxes of 5 °M Warmers (MWS201):

Expiry date [yyymmdd]	LOT on box label (code (10) in the QR code)
270620	65633, 65697, 65698, 65699, 65700, 65716, 65717, 65718, 65719, 65826, 65827
270728	65827, 65828, 65829, 65853, 65854, 65877, 65878, 65880, 65881, 65947, 65948, 66074
270907	66074, 66075, 66076, 66077, 66078, 66079, 66229, 66230, 66232, 66233, 66269, 66270, 66271, 66272, 66295, 66296, 66357
271124	66357, 66358, 66419, 66420, 66471, 66472, 66473, 66474, 66496, 66601, 66847, 66848
271213	66496, 66534, 66601, 66847, 66848
280123	66848, 66849, 66850, 66884, 67105
280206	66851, 66855, 66869, 66884, 67105
280308	66869, 66884, 66952, 66987, 66988, 67682
280322	66987, 66988
280410	66988, 67031, 67105, 67107, 67682
280419	67107, 67297, 67682
280425	67297, 67312, 67682
280513	67312, 67346, 67347, 67461
280607	67347, 67461
280612	67461, 67467, 67468, 67682, 67841



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Overview of affected individual °M Warmers (MWS201W):

Expiry date [yyymmdd]	LOT on pouch label (code (10) in the QR code)
270620	65497, 65498, 65499, 65634, 65709, 65823
270728	65823, 65824, 65825, 65876, 65879, 65946, 66064
270907	66064, 66065, 66066, 66228, 66231, 66266, 66267, 66268, 66356
271124	66356, 66418, 66469, 66470, 66495, 66533, 66858
271213	66495, 66533, 66600, 66858
280123	66858, 66859, 66860, 67241
280206	66860, 66861, 66862, 66863, 67241
280308	66863, 66868, 66951, 66985, 67381
280322	66985, 66986
280410	66986, 67239, 67241, 67242, 67381
280419	67242, 67296, 67381
280425	67296, 67311, 67381
280513	67311, 67348, 67349, 67464
280607	67349, 67460
280612	67460, 67462, 67681, 67830

