

2026-06-24

URGENT FIELD SAFETY NOTICE**Manufacturer:** Maquet Cardiopulmonary GmbH (SRN: DE-MF-000020091)**FSCA Reference:** 1553581 - HKH 8820 Wall Holder – Labeling incorrect**FSN Type:** New**Affected Product:** HKH 8820 Wall Holder (Mat. 701045366)**Unique Device Identifier:** 04037691456584

Affected Serial No.:	98820448	98820504	98820510
	98820493	98820505	98820514
	98820494	98820507	98820515
	98820496	98820508	98820516
	98820498	98820509	98820521

For Attention of: Users of the medical device listed above

Dear valued customer,

The purpose of this letter is to advise you that Maquet Cardiopulmonary GmbH (MCP), a subsidiary of Getinge, is voluntarily reworking certain HKH 8820 Wall Holders due to incorrect labeling.

The HKH 8820 Wall Holder is a mounting bracket that was designed to be permanently installed in a road vehicle for the inter-hospital transport of the CARDIOHELP-i system by enabling a secure attachment of the CARDIOHELP-i to the vehicle.



Figure 1: Picture of CARDIOHELP system

(left: HKH 8820 Wall Holder, center: CARDIOHELP-i being attached to HKH 8820 Wall Holder, right: mounted system)

Actions to be taken by the manufacturer:

<input type="checkbox"/> Product Removal	<input type="checkbox"/> On-site device modification/ inspection
<input type="checkbox"/> Software Upgrade	<input checked="" type="checkbox"/> IFU or labeling change
<input checked="" type="checkbox"/> Other	<input type="checkbox"/> None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- For customers with maintenance contract:
Replacement of the Type Label) for the customer.
- For customers without maintenance contract:
The local Getinge representative will contact the customer to arrange the replacement of the Type Label .

Enclosed documents:

- Letter of Acknowledgment Customer

Transmission of the Field Safety Notice:

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Vice President

Signature:

Electronically signed by: Dieter Engel
Reason: I approve this document.
Date: Jun 25, 2025 10:14:19 GMT+2

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature:

Electronically signed by: Alexander Bernhardt
Reason: I approve this document.
Date: Jun 24, 2025 14:38:45 GMT+2

Email: alexander.bernhardt@getinge.com

Contact details of manufacturer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference: 1553581 - HKH 8820 Wall Holder – Labeling incorrect

Affected Product: HKH 8820 Wall Holder (Mat. 701045366)

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Please send this form at the latest by **July 17, 2026**, to your local Getinge representative.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected staff.
- I have no affected products in my inventory.
- I have the following affected products in my inventory:

Article Number	Description	Serial Number	Quantity
XXXXX.XXXX	<SAP Product name>		

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email [enter local Getinge mail address](#) or via post [enter local Getinge address](#) or FAX>: