

To our customers

St. Egidien, December 4, 2024

## Important safety corrective measure FSCA-hm-2024-0101

Ladies and Gentlemen,

As part of our post-market surveillance, we have conducted further tests for the product *Hissin Space mount*, which hestomed continued to market under the name *redmount. mounting bracket Space mount* after the acquisition of Hissin Medizintechnik GmbH and found that the results do not meet our quality requirements. Using the applicable standard *DIN EN 1789 Medical vehicles and their equipment - Road ambulances*, the following design change was made:

- - New design of the swivel adapter and thus increased strength

As an accessory for the *redmount. mounting bracket space*, an optional *swivelling retaining claw Art. No. H14617* can be used to connect the *redmount. mounting bracket space* with a maximum of three interconnected *redmount. mounting bracket space/ redmount. mounting bracket space plus* to round tubes or rails. The standard *DIN EN 1789 Medical vehicles and their equipment - Road ambulances* specifies an acceleration or deceleration test of 10 g for use in rescue service vehicles.

This test was carried out in accordance with current standard specifications for the product *redmount. mounting bracket space*. It was found that the accessory *swivelling mounting claw Art. No. H14617* does not fulfil all the requirements of this standard. hestomed is therefore unable to ensure compliance with the requirements of *DIN EN 1789* for the *swivelling mounting claw, Art. No. H14617* previously supplied under Hissin Medizintechnik and hestomed GmbH. hestomed has not received any report of an incident, patient or user injury in this context.

According to our records, you have received one or more devices from the affected serial number range from us.

Please ensure that all users of the *swivelling mounting claw Art. No. H14617* and other affected persons in your organisation take note of this important safety information.

If you have made the products available to third parties, please forward a copy of this important safety notice.

**The *swivelling mounting claw Art. No. H14617* can continue to be used until it is replaced.** There are no restrictions on the products supplied to date.



You will be contacted by hestomed as soon as the improved and successfully tested *swivelling mounting claw* is available. The replacement can be carried out by the user. Deliveries will take place from Q1 / 2025.

To confirm this, please complete the enclosed reply form and return it to us.

We regret any inconvenience this information may cause you.

Please retain this important safety instruction at least until the *swivelling mounting claw* has been replaced.

The relevant authorities were informed of the action.

If you have any questions, please contact the regulatory department of hestomed GmbH using the following contact options:

Tel. +49 (0) 37204 / 638 - 18      Mail. [f.wagner@hestomed.de](mailto:f.wagner@hestomed.de)

With kind regards  
hestomed GmbH

04.12.2024

Dirk Rothschild  
CEO

04.12.2024

Felix Wagner  
QMB; Regulatory affairs

Attachments:

Appendix A - to the important safety notice - affected devices

Appendix B - to the important safety notice - Conversion instructions

Appendix C - to the important safety notice - reply letter

## Appendix A - to the important safety notice - affected devices

<b>Accessories</b>	<b>Manufacturer/ Article no.</b>	<b>Lot numbers</b>	<b>Delivery time</b>
swivelling mounting claw	hestomed GmbH H14617	12/2023	2023
swivelling mounting claw	Hissin Medizintechnik GmbH 14617	No limitation	2013 - 2023

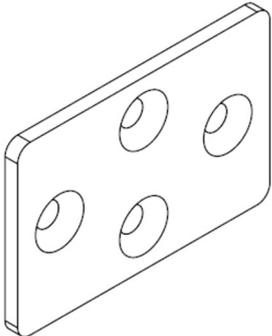
Appendix B - to the important safety notice - Conversion instructions

## Replacement instructions redmount. mounting bracket space

### Replacing the swivelling mounting claw (only for devices with previous swivelling mounting claw)

Materials required:

Conversion kit (provided by hestomed) consisting of:

(1) Swivel adapter, new	
(2) Counter plate, new	
(3) Screw (M5x8 with TUFLOK® 360°), 4 pieces	No illustration

Tools (provided by the customer/service partner):

- Suitable spanner

## Procedure

<p><b>Step 1:</b></p> <p>Remove any syringe pumps from the holder. Detach the holder from the rail/round tube and place it on a firm work surface.</p>	
<p><b>Step 2:</b></p> <p>Remove the old rotary adapter together with the retaining claw by completely loosening the screws from the internal counter plate. The cross groove on the rear wall of the housing should now be exposed. (see illustration) Set the dismantled rotary adapter and retaining claw aside for step 6.</p>	
<p><b>Step 3:</b></p> <p>Position the new swivel adapter (1) with its cross profile behind the cross groove. (see illustration) The unlocking bolt must be positioned so that it is easy to reach. Depending on the installation, it can point upwards or downwards from the initial position.</p>	
<p><b>Step 4:</b></p> <p>Position the new counter plate (2) from the inside of the housing with the holes congruent over the threaded holes of the rotary adapter (1). The countersinks must point towards the inside of the housing. Using a suitable spanner, screw the enclosed screws (3) from the inside of the housing of the appliance holder through the counter plate (2) into the swivel adapter (1)</p>	
<p><b>Step 5:</b></p> <p>Screw in the threads of the screws completely until the screw head is fully in the countersink and tighten them hand-tight. The swivel adapter (1) should now be screwed onto the device holder without any gaps</p>	

<p>(see fig.) The screw coating with TUFLOK® 360° secures the screws in the thread against unintentional loosening.</p>	
<p>Step 6: Remove the retaining claw from the removed (old) swivel adapter by opening it completely and loosening the 4 visible screws.</p>	
<p>Step 7: Fit the removed retaining claw to the new swivel adapter (1) on the side facing away from the device holder. Follow the separate installation instructions for the retaining claw</p>	



## Appendix C - to the important safety notice - reply letter

## Reply letter

Please return the completed reply form by e-mail or post:

**Mail** **f.wagner@hestomed.de**

**Post** **hestomed GmbH**  
**Regulatorische Angelegenheiten**  
**Am Eichenwald 13**  
**09356 St. Egidien**

- We confirm receipt of the important safety notice and its distribution to all affected users in our organisation or third parties.
- We are no longer in possession of the product
- We request the replacement of \_\_\_\_\_ piece of the swivelling mounting claw

**Organisation** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Contact person** \_\_\_\_\_

**Telephone** \_\_\_\_\_

**Mail address** \_\_\_\_\_

**Date** \_\_\_\_\_

**Signature** \_\_\_\_\_