

Complaint No.
KR20180903-1

HOGGI[®]

HOGGI GmbH
Eulerstraße 27
D-56235 Ransbach-Baumbach

Urgent safety information

Recall

concerning

Wheelchair CLEO Ti

18.10.2018

Sender:

HOGGI GmbH, Eulerstr. 27, 56235 Ransbach-Baumbach

Addressee:

To all retailers and export customers

Identification of the affected medical devices:

- Wheelchair with tilt function CLEO Ti (see serial numbers in the attachment).
- delivered in the period from 18.01.2018 to 29.08.2018.

Description of the problem including the identified cause:

- HOGGI strives to improve your product quality to ensure the safety of users and their companion in every respect.
- As part of the market observation, HOGGI became aware of a weak point of sheet metal carriers. These are only the seat plate carrier of a certain version and batch. Thus, the amount of affected wheelchairs could be determined. However, not all wheelchairs listed in the attachment are affected. For this reason, it makes sense to send the pictures of the left and right seat plate carrier from each wheelchair listed in the attachment to a dealer or to HOGGI first to identify whether the wheelchair is affected. (which area needs to be photographed is explained below and depicted pictorially).

Illustration-1



Illustration-2



Since the risk for users to be injured due to the breakage of the seat plate carrier is too high, seat plate carriers in affected wheelchairs must be replaced as quickly as possible.



HOGGI

Complaint No.
KR20180903-1

HOGGI[®]

HOGGI GmbH
Eulerstraße 27
D-56235 Ransbach-Baumbach

Action to be taken by the addressee:

- After receiving this information, identify the end customer based on serial numbers and commissions in the attachment.
- Immediately inform the end customers to check the seat plate carrier and ask to create the pictures from both sides (which area needs to be photographed is explained below and depicted pictorially).
- Customer-generated images of seat plate carrier must be returned to dealer or to HOGGI to identify the seat-plate carrier.
- Advise customers to monitor / control the affected area daily until replacement.
- Confirm that all customers have been informed of the affected wheelchairs, send them to HOGGI.
- Request the conversion kits from HOGGI free of charge with the request form.
- Rebuild affected wheelchairs as soon as possible.
- Fill out confirmation form to have carried out the conversion of affected wheelchairs, with serial numbers and send them to HOGGI (see attachment).

Passing on the information described here:

Please make sure in your organization that all users of the mentioned products and other persons to be informed have been informed of this **Urgent Safety Information**. If you have given the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please retain this information at least until the action has been completed.

Contact person:

Jan Frank

frank@hoggi.de

+49 (0) 2623 92 499 21

Thank you in advance for your effort.

Kind regards

Jan Frank

Attachments:

- A1- Description of the affected seat plate carrier.
- A2- Confirmation form for corrective action.
- A3- Request form for free conversion kit.
- A4- Confirmation form of the carried out reconstruction.

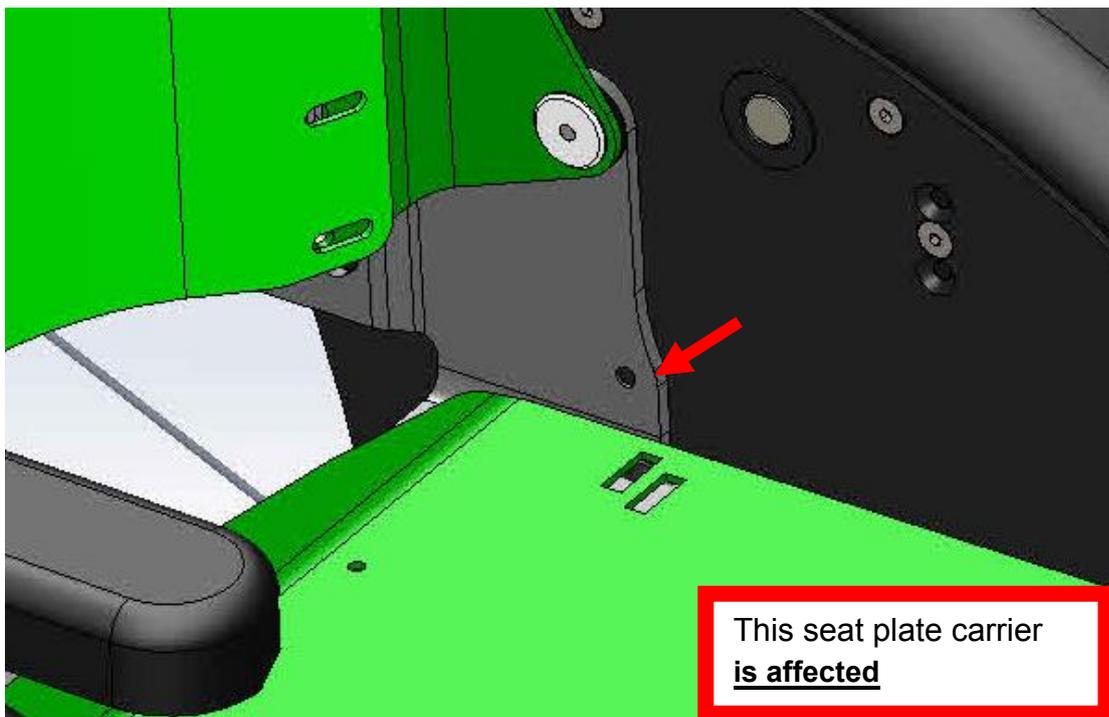
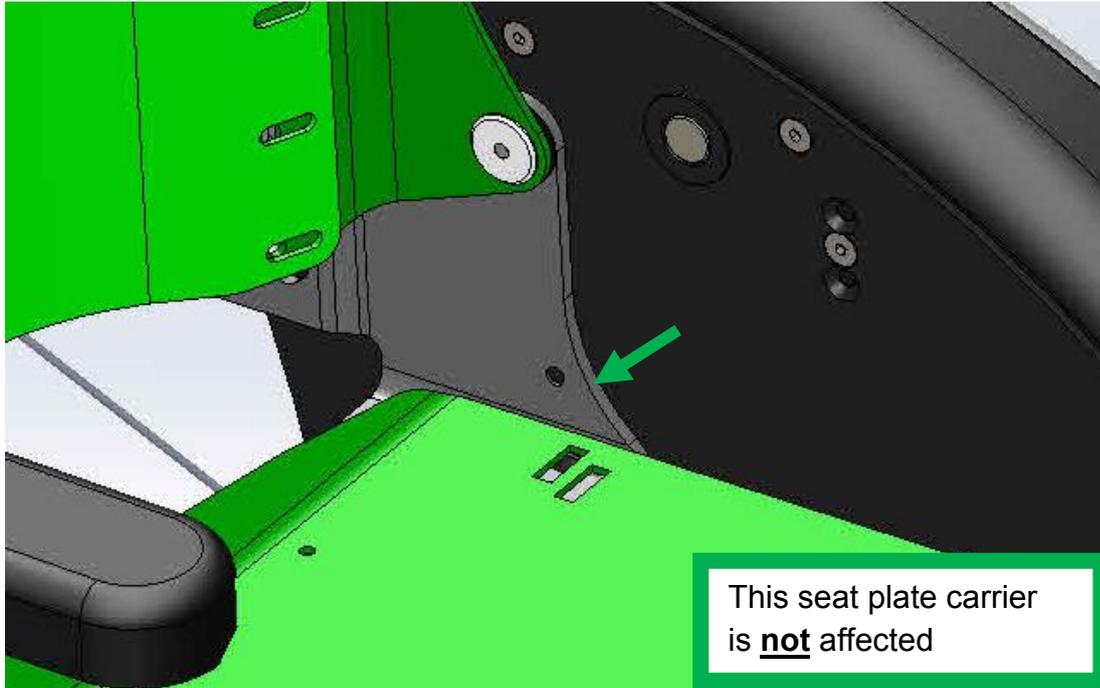
The image shows the HOGGI logo in a large, blue, stylized font. The letters are bold and rounded. To the right of the logo is a registered trademark symbol (®).

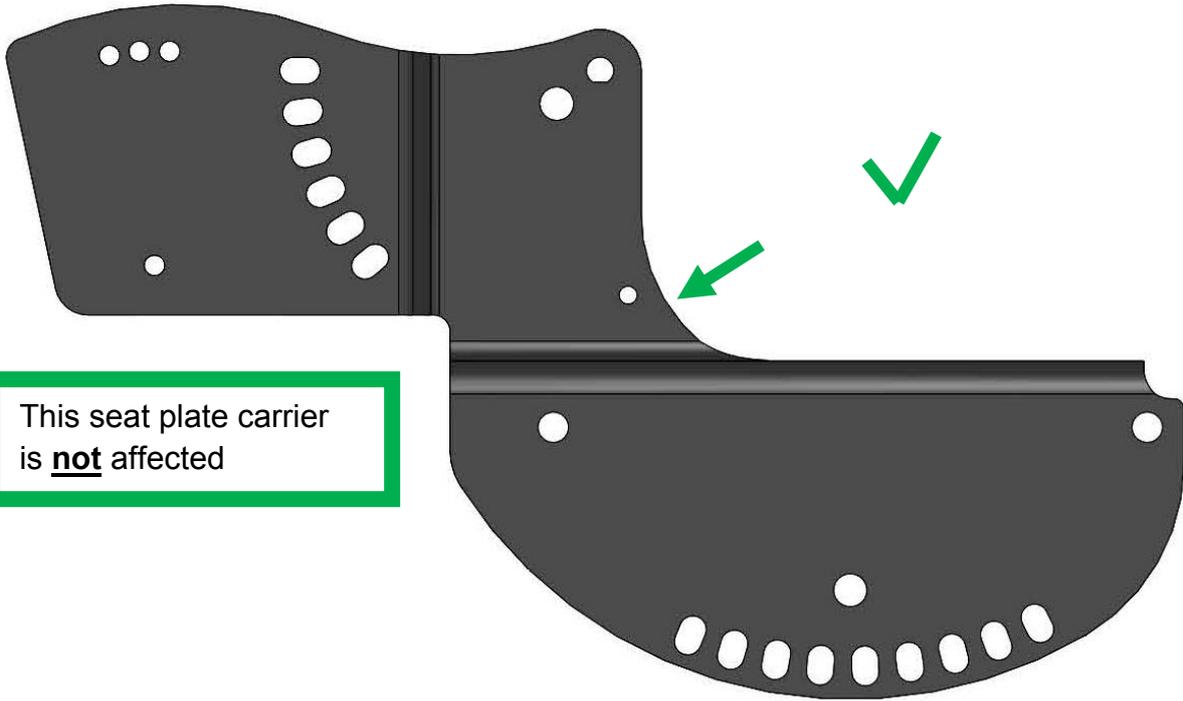
A1

Description of the affected seat plate carrier

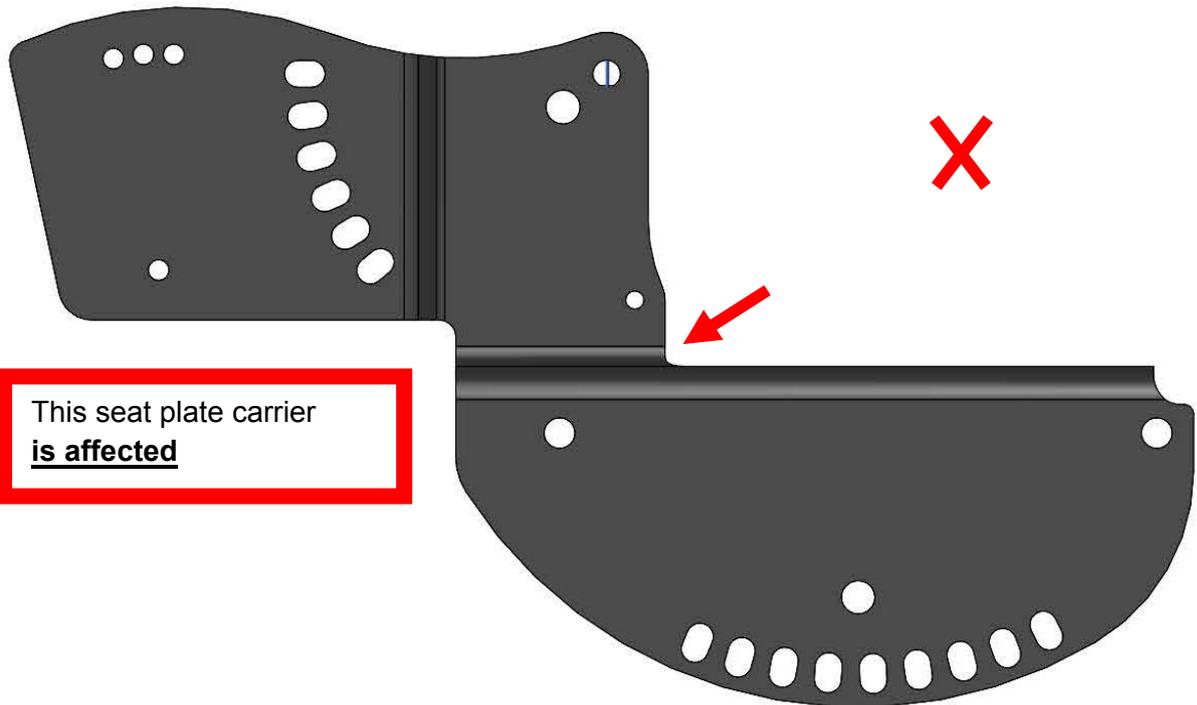
How to find out which seat plate carrier is installed on the wheelchair?

The seat plate carrier is a supporting component to which the seat plate and the back plate are attached. After removing the seat cushion, it is visually recognizable at the radius which seat plate carrier is installed:





This seat plate carrier
is not affected



This seat plate carrier
is affected

Complaint No.
KR20180903-1

A2
Confirmation form for corrective action
seat plate carrier CLEO Ti

Customer number _____
Customer name _____

We hereby confirm that all users of the product named in the safety information and other persons to be informed have received knowledge of this safety information regarding the conversion of seat plate carriers.

for wheelchairs with the following serial numbers

(Serial number can be found here)



Best regards

Name

Signature

Complaint No.
KR20180903-1

A3
Request form for free conversion kit
seat plate carrier CLEO Ti

Dear Sirs and Madames,

please send us

_____x Conversion kit seat plate carrier left and right for CLEO Ti
Amount

for wheelchairs with the following serial numbers

(Serial number can be found here)



to the following address:

Best regards

Name

Signature



