

## Field Safety Notice

### Küschall manual wheelchairs manufactured between 12<sup>th</sup> October 2016 and 20<sup>th</sup> December 2016

Date: 20<sup>th</sup> January 2017

Invacare ref: 584163

MHRA ref: 2017/001/017/701/029

#### Important Information:

Dear Customer

We would like to bring to your attention that the manual wheelchairs manufactured in the above mentioned period were fitted with labels that are not in accordance to our quality standards. The print on the label can be accidentally removed by rubbing on the label or by using a commercially available cleaner.



Example of a partly removed imprint

The safe use of the product is not affected. No potential harm for the user can arise through this error.

Together with this Field Safety Notice Letter you receive a new serial label which shall replace the affixed one on the frame.

In order to replace the label, please remove the affixed one from the frame of the wheelchair by peeling it off thoroughly. To get a smooth surface all label parts should be properly removed. In case the label sticks too tight on the frame, you can support the removal by slightly warm up the frame and/or the label.

Clean the surface of the frame by using a commercially available cleaning liquid. Be careful not to use too aggressive media (e.g. Acetone, Benzine), otherwise the coating of the frame can be damaged.

Peel off the new label from its carrier foil and place it on the frame.

Use the attached Customer Response Letter to inform Invacare Ltd (Fax number below) about the completion of the Field Safety Corrective Action.

Please ensure that the information in this notice is made available to all relevant personnel within your organization and / or customer base, and that awareness is maintained for an appropriate period.

Invacare confirms that the relevant Competent Authorities have been informed of this Field Safety Notice.

If you have any questions relating to this Field Safety Notice, or should you require any additional information, please contact;

### **Technical Services Department**

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# Customer Response to Field Safety Notice

## FSN 584163 – Kuschall wheelchairs – replace serial number label

This is to confirm that the necessary corrective action, as documented in the Field Safety Notice, FSN 584163, dated 20/01/2017, is now under way and completed for devices documented below.

Serial Number(s) of completed units:

**Please send fax-back form to the relevant Invacare office (as below).**

### Action Completed

Signed.....

Company.....

Contact No.....

Date.....

**You have a responsibility under the Medical Device Directive to notify the manufacturer when corrective actions have been completed.**

**Where appropriate, please provide Invacare with monthly updates.**