Urgent Field Safety Notice

Invacare REA Focus, Spirea and SpinX – Incomplete labels

Date: 3rd June 2014

Invacare incident ref: TRW 109179
MPA reference: 6.6.4-2014-45116

Important Safety Information:

In the interests of the safety of our customers we would like to bring your attention to the serial labels of Invacare wheelchairs REA Focus, Spirea and SpinX.

Invacare REA Focus, Spirea and SpinX are manufactured at Invacare REA, Sweden. The wheelchairs comply in full with all applicable requirements for Medical devices, class 1 products, according to Medical devices directive 93/42/EEC. The wheelchairs have all been declared to meet the directive and have been registered at SE-MPA the Swedish Medical Products Agency, since sales start.

Due to usage of a wrong label roll within the printer during February 1, 2012 to May 25, 2012, the CE-logo and the maximum user weight are lacking from the serial label placed on the products during this time.

List of affected wheelchairs, complementary labels and instructions will be sent to the local Invacare sales companies, who provides these further to their affected customers. Local sales companies are kindly asked to report back to Invacare REA when this is done, using the attached Fax back.

Affected customers are kindly asked to add the supplementary label with CE-Logo and maximum user weight to the affected Invacare REA wheelchairs Focus, Spirea and SpinX.

More labels and instructions can be ordered from your Invacare representative free of charge. What part number to use when ordering depends on wheelchair model, see table below.

Model	Max user weight	Part number
REA Focus 150	Max 150 kg	1582712
REA Focus (all other variants)	Max 135 kg	1582711
REA Spirea 2 (all variants)	Max 125 kg	1582653
REA Spirea 3	Max 135 kg	1582711
REA Spirea 4 NG	Max 135 kg	1582711
REA Spin-X	Max 125 kg	1582653

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

Invacare acknowledges that this may be an inconvenience; however it is not an option and must be done immediately to mitigate the potential safety risk.

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

Technical Services Department

Tel. :
Fax. :

INSERT LOCAL INVACARE REPRESENTATIVE ADDRESS.

Invacare confirm that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.