

To whom it may concern,

Invacare initiates a Field Safety Corrective Action involving the Invacare Dolomite Gloss rollator as we identified that a limited quantity of rollators is not behaving as intended when intensively used, or when subject to strong external impacts.

The Gloss rollator has been tested and conforms to fatigue and static loading tests according to applicable standards. However, it was found that the durability of the seat may be impacted with a possible adverse effect on its resistance. Therefore, Invacare has decided to replace the crossbar on the affected Invacare Dolomite Gloss rollators in the field, by a new improved and more resistant crossbar.

To give a timeline for the execution of this Field Safety Corrective Action, I hereby inform you that Invacare and the Medical Products Agency (MPA) Sweden, agreed that the affected devices shall be corrected as soon as possible, but no later than December 2024.

4th January 2024

Madeleine Gloy

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VP QA RA EMEA and APAC Invacare International GmbH