Raz Design Inc.
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URGENT FIELD SAFETY NOTICE

FSN Reference number: 2611-01 **Date:** 2026-11-04

Dear Valued Customer,

Your client's safety is our top priority at Raz Design Inc. (Raz). Our records indicate that you have received one or more of the Raz Shower Commode Chairs listed in Table below. The purpose of this Field Safety Notice (FSN) is to advise you that Raz is conducting a voluntary Field Safety Corrective Action (FSCA) of certain seats of Raz Shower Commode Chairs in the European Union (EU).

	1. Information on Affected Devices
1.	**1. Following are the affected devices** The affected Molded and VFI seats were supplied on the following chair models:

Product Name and Description	Chair Catalogue Number	UDI (Unique Device Identifier)
Raz-AT (Attendant Tilt) Mobile Shower Commode Chair	Z300	(01)00628758003007
Raz-SP (Self Propel) Mobile Shower Commode Chair	Z200	(01)00628758002000
ZUM-SP Mobile Shower Commode Chair	Z222	(01)00628758002222
Raze Shower Commode Chair	Z444	(01)00628758004448

Catalogue Numbers of the Affected Seats:

ZVFI17RTO, ZVFI20LTO, ZVFI17FRO, ZVFI20RRO, ZVFI20RTO-A, ZVFI20FRO, ZMS17FRO-A, ZVFI20BRI, ZMS17FRO

1.	**2. Intended Use** Raz Shower Commode Chairs and Tub Sliders are intended as an aid for showering/bathing, toileting and personal hygiene for people with mobility impairments, with or without the assistance of a caregiver, in indoor environments only.

	2. Reason for Field Safety Corrective Action (FSCA)
2.	**1. Description of the product problem** On Oct 28, 2026, it was determined certain seats produced for Raz were not built to Raz's specifications. The substandard seats were discovered at Raz. All impacted seats at Raz were immediately quarantined. No adverse incidents or customer complaints have been reported as of Nov 04, 2026.
2.	**2. Health hazard evaluation and corrective action** When manufactured according to Raz's specifications, the Molded and VFI Seats on the Raz Shower Commode Chair meet performance requirements.

	2. Reason for Field Safety Corrective Action (FSCA)
	Raz is conducting a voluntary FSCA to prevent the affected Molded and VFI seats from reaching clients. Molded and VFI seats that are not built to the proper specifications can break and potentially result in injuries. The voluntary FSCA includes a Raz-approved replacement seat, which will be sent to each impacted client at Raz's expense. All impacted seats must be destroyed with photographic documentation as evidence. The photos must be sent to Raz at arahat@razdesigninc.com.

	3. Type of Action to mitigate the risk
3.	**1. Action being taken by the Manufacturer** a) Notify impacted customers using this Field Safety Notice and request them to return the ***Acknowledgement and Receipt Form*** to arahat@razdesigninc.com promptly and no later than **05 calendar days** from the receipt of this Field Safety Notice. b) Provide the following items to facilitate this FSCA: i. Replacement Molded / VFI Seat(s) ii. Replacement Seat Installation Instruction Sheet iii. Acknowledgement and Receipt Form c) Investigate the root cause with the seat supplier and update the risk management file as needed.
3.	**2. Action to be taken by the Importer / Distributor** a) Fill out and return the ***Acknowledgement and Receipt Form*** to arahat@razdesigninc.com promptly and no later than **05 calendar days** from the receipt of this Field Safety Notice. b) Please notify your impacted clients using this Field Safety Notice and request that they return the ***Acknowledgement and Receipt Form*** to you. Any adverse events noted on the ***Acknowledgement and Receipt Form*** must be reported to Raz immediately: arahat@razdesigninc.com. c) Raz is providing the following items to facilitate this FSCA. The items will be provided directly to the Importer / Distributor, who will execute the action: i. Replacement Molded / VFI Seat(s) ii. Replacement Seat Installation Instruction Sheet iii. Acknowledgement and Receipt Form d) Conduct a service appointment with the impacted client and perform the following: i. Review the Instruction Sheet. ii. Install the Replacement Seat. iii. Destroy the affected Seat and take photographs as evidence. e) Retain a record of this Field Safety Notice and all ***Acknowledgement and Receipt Forms*** signed by clients, along with photographs of the destroyed seats. Send this documentation to Raz Design at arahat@razdesigninc.com.
3.	**3. Action to be taken by the User / Caregiver / Primary Contact** a) Immediately stop using the chair with the affected seat. b) You will be contacted to schedule a service appointment. During the appointment: i. The replacement seat will be installed. ii. You will be asked to sign the ***Acknowledgement and Receipt Form***. iii. The affected seat will be destroyed and photographed.

	3. Type of Action to mitigate the risk
	c) For further information, please contact your Importer / Distributor.

	4. Serious Incident Reporting
4.	If any serious incident occurs in relation to this device, meaning any event that has led, or could lead, to death, serious injury, or serious deterioration in health, it must be reported without delay to: • The manufacturer (contact details provided in the User and Dealer Manual (Instructions for Use)), and • The national competent authority of the EU Member State where the user or patient is located.

	5. List of attachments
5.	• Acknowledgement and Receipt Form. • Replacement Seat Installation Instruction Sheet. • EU Affected Units Distribution Record List with Consignee Details.

	6. Contact Details
6.	For further information or help with this FSCA, please reach out to Raz Design Inc. by email at arahat@razdesigninc.com. This notice has been reported to the relevant national competent authority(ies) through Raz's EU Authorized Representative. Raz regrets any inconvenience caused by this FSCA. Best Regards, Arslan Rahat Arslan Rahat Quality and Regulatory Affairs Manager

	Transmission of this Field Safety Notice
	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness of this notice and the resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.