

STANDARD INFORMATION

Standard: CSA Z316.6

Standard ID: Sharps Injury Protection - Requirements and Test Methods-Sharps Containers [CSA Z316.6:2020 Ed.5]

Previous Standard ID: Sharps Injury Protection - Requirements and Test Methods-Sharps Containers (R2019) [CSA Z316.6:2014 Ed.4]

EFFECTIVE DATE OF NEW/REVISED REQUIREMENTS

Effective Date: **May 1, 2024**

IMPACT, OVERVIEW, AND ACTION REQUIRED

Impact Statement: Per our accreditation, Intertek is required to review reports against the standard revisions to confirm compliance. Once compliance is confirmed, the standard reference in the report is updated to show continued compliance to the technical requirements of the standard. Reports not updated to this version by the effective date above will be withdrawn.

Overview of Changes:

- Addition of requirements for lifespan simulation prior to testing
- Addition of requirements for resistance to spillage by toppling
- Addition of requirements for quality monitoring: post decontamination quality assurance

Specific details of new/revise requirements are found in table below.

Current Listings Not Active? – Please immediately identify any current Listing Reports or products that are no longer active and should be removed from our records. We will do this at no charge as long as Intertek is notified in writing prior to the review of your reports.



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CLAUSE	VERDICT	COMMENT
		<i>Additions to existing requirements are <u>underlined</u> and deletions are shown lined out below.</i>
		<i>New section added;</i>
4		Requirements and recommendations See standard for details.
		<i>New section added;</i>
5		Lifespan simulation prior to testing Lifespan simulation shall be conducted on a sufficient number of reusable sharps containers. See standard for details.
6	Info	Test methods
6.3	Info	Resistance to penetration
6.3.2	Info	Procedure Determine the worst case area for needle penetration of the sharps containment surface in the final closure configuration. Determine the number of test specimens for testing. Cut test specimens of approximately 12 mm × 12 mm from this area.
6.3.2.1		<u>Cut the entire external surface of the container into 24 approximately equal sized areas. In each of these 24 areas, measure the thickness in order to determine where it is thinnest. Conduct the penetration test on the thinnest part of each of these 24 test specimen. Where containers are too small to obtain 24 samples, use more than 1 container.</u>
6.4	Info	Resistance to damage and leakage after dropping
6.4.2	Info	Procedure Fill the sharps container with a volume of water at (23 ± 5) °C equal to 1 % of the volume at the fill line indicator of the container. Fill the container to the fill line with representative sharps or a substance of density (0,2 ± 0,02) kg/l. If a substance with a different density is used, the target mass should be equivalent to that of the container filled to the fill line with representative sharps. Sharps containers that are commercially available with an absorbent material (i.e. absorbent pad/sachet) to assist leak resistance, shall be tested with this material in the container. Close and permanently secure the aperture for final disposal. Leave the container to stand for 1 h.
6.4.2.2		<u>Fill the sharps container with a volume of water at (23 ± 2) °C equal to 1 % of the volume measured to the fill line of the container. In addition, fill the sharps</u>



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		<p><u>container with a weight of PE/PP granules equal to 100 % of the manufacturer's maximum allowable gross mass.</u></p> <hr/> <p>The procedure for all containers is as follows.</p> <p>Follow steps a) to d) for each of the following orientations: base, side wall, adjacent side wall, <u>top, a lower corner for a rectangular base, or a bottom edge for a round base and an upper corner (area of lower resistance, closure or gripping means).</u></p> <p>a) Position the container at the proper height and in the desired orientation for the impact fall. b) Release the container. Do not obstruct its fall or restrict movement of the container after it has struck the impact surface. c) Examine the sharps container for integrity and evidence of leakage/wetting of the outer surface of the container and/or wetting of the impact surface. d) Repeat the procedure in a different orientation (as described above) using a new container for each test.</p> <p><u>Check for conformity with the requirements in 4.2.6.</u></p> <hr/> <p><i>New section added;</i></p>
6.4.2.4		
6.5		<p>Resistance to spillage by toppling</p> <p>See standard for details.</p> <hr/> <p><i>New section added;</i></p>
7		<p>Quality monitoring: Post decontamination quality assurance</p> <p>To maintain good manufacturing practice and meet user requirements, the processor of reusable sharps containers shall have in place work practice procedures and controls. See standard for details.</p> <hr/>
8	Info	<p>Labelling and marking and instructions for use</p> <hr/> <p>Labelling and marking</p> <p>[Replace Item c) with the following]</p>
8.1		<p>c) identification of the specific use of the container as follows: <u>3) Pharmaceutical sharps containers:</u> <u>Sharps containers intended to contain pharmaceutical sharps shall prominently display the pharmaceutical hazard symbol as shown in Figure 3A or 3B, or equivalent. The pharmaceutical hazard symbol shall display an "Rx" as its image and shall contain the words "PHARMACEUTICAL/ PHARMACEUTIQUE" as its legend. The elements of the pharmaceutical hazard symbol and the legend shall be displayed in blue on white or white on blue;</u></p>



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		<p>i) warning regarding:</p> <ul style="list-style-type: none"><u>1) fill capacity: every sharps container, other than pocket collectors, shall have the warning statement “DO NOT OVERFILL/NE REMPLISSEZ PAS AU-DESSUS DE CETTE LIGNE”, or the equivalent, prominently and permanently displayed on its outer surface;</u><u>2) “not forcing sharp into sharp container”;</u><u>3) “Use only with secondary stabilizer”, when the container is designed for use with a secondary stabilizer.</u> <p>j) <u>containers meeting UN packaging requirements shall be marked accordingly;</u> k) <u>containers requiring assembly shall have clear assembly instructions or pictograms to enable users to attach the top securely and fully to the base.</u></p> <hr/> <p>Instructions for use</p> <p>The instructions for use shall describe the manufacturer's recommendations for intended use of the container. Drawings, pictograms or other graphical aids may be used where applicable.</p> <p>Instructions for use shall include the following, as applicable:</p>
8.2		<p>f) <u>the manufacturer's allowable gross mass in kg;</u> g) <u>any other warnings or precautions that the manufacturer deems appropriate to assist the user in the safe use of the container;</u> h) <u>if containers have a needle disconnect system and needle-disconnection is clinically required, needle-disconnection shall be achievable with one hand and manufacturers shall advise whether a secondary stabilizer should be used during the disconnection procedure;</u> i) <u>if users are required to utilize the container on a horizontal surface, manufacturers shall advise whether a secondary stabilizer is required;</u> j) <u>packaging information as appropriate (e.g. mail back program)</u></p> <hr/>