Doc No: MHD 12 (25444) WC
May 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

जीवाणुरहित पैकेज्ड भरने के लिए तैयार ग्लास कार्ट्रिज

Draft Indian Standard

Sterile Packaged Ready for Filling Glass Cartridges

ICS 11.080.30

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	Last date for comments: **07 June 2024**

NATIONAL FOREWORD

(*Adoption clause will be added later*)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 720, Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification	IS 2303 (Part 1/Sec 2) : 2021/ISO 720 : 2020, Grading Glass for Alkalinity Part 1 Hydrolytic Resistance of Glass Grains Section 2 Determination and classification	Identical

	of hydrolytic resistance at 121°C (*Third Revision*)	
ISO 10993-7, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	IS/ISO 10993-7 : 2008, Biological Evaluation of Medical Devices Part 7 Ethylene Oxide Sterilization Residuals	Identical
ISO 11138-1, Sterilization of health care products — Biological indicators — Part 1: General requirements	IS/ISO 11138-1 : 2017, Sterilization of Health Care Products — Biological Indicators Part 1 General Requirements	Identical
ISO 11138-2, Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes	IS/ISO 11138-2 : 2017, Sterilization of Health Care Products — Biological Indicators Part 2 Biological Indicators for Ethylene Oxide Sterilization Processes	Identical
ISO 11138-3, Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes	IS/ISO 11138-3 : 2017, Sterilization of Healthcare Products — Biological Indicators Part 3 Biological Indicators for Moist Heat Sterilization Processes	Identical
ISO 11138-4, Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes	IS/ISO 11138-4 : 2017, Sterilization of Health Care Products — Biological Indicators Part 4 Biological Indicators for Dry Heat Sterilization Processes	Identical
ISO 11138-5, Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	IS/ISO 11138-5 : 2017, Sterilization of Health Care Products — Biological Indicators Part 5 Biological Indicators for Low-Temperature Steam and Formaldehyde Sterilization Processes	Identical
ISO 11138-7, Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results	IS 18469 (Part 7) : 2023/ISO 11138-7 : 2019, Sterilization of Health Care Products — Biological Indicators Part 7 Guidance for the Selection Use and Interpretation of Results	Identical
ISO 11138-8, Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator	IS 18469 (Part 8) : 2023/ISO 11138-8 : 2021, Sterilization of Health Care Products — Biological Indicators Part 8 Method for Validation of a Reduced Incubation Time for a Biological Indicator	Identical

ISO 11140-1, Sterilization of health care products — Chemical indicators — Part 1: General requirements	IS 18446 (Part 1) : 2023, Sterilization of Health Care Products — Chemical Indicators Part 1 General Requirements (ISO 11140-1 : 2014, MOD)	Modified
ISO 11140-3, Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	IS/ISO 11140-3 : 2007, Sterilization of Health Care Products — Chemical Indicators Part 3 Class 2 Indicator Systems for Use in the Bowie and Dick-Type Steam Penetration Test	Identical
ISO 11140-4, Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	IS/ISO 11140-4 : 2007, Sterilization of Health Care Products — Chemical Indicators Part 4 Class 2 Indicators as an Alternative to the Bowie and Dick-type Test for Detection of Steam Penetration	Identical
ISO 11140-5, Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests	IS/ISO 11140-5 : 2007, Sterilization of Health Care Products — Chemical Indicators Part 5 Class 2 Indicators for Bowie and Dick-Type Air Removal Tests	Identical
ISO 11140-6, Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers	MHD/12/23986, Sterilization of Health Care Products Chemical Indicators Part 6 Type 2 Indicators and Process Challenge Devices for Use in Performance Testing of Small Steam Sterilizers	Identical
ISO 11607-1, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	IS/ISO 11607-1 : 2019, Packaging for Terminally Sterilized Medical Devices Part 1 Requirements for Materials, Sterile Barrier Systems and Packaging Systems (*First Revision*)	Identical
ISO 13926-1:2018, Pen systems — Part 1: Glass cylinders for pen-injectors for medical use	IS/ISO 13926-1 : 2018, Pen Systems Part 1 Glass Cylinders for Pen-Injectors for Medical Use	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 8871-1	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates
ISO 11608-3	Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Scope

This document specifies the characteristics of sterile and ready for filling empty glass cartridges for injectable preparations, including the minimum requirements of materials, packaging systems and analytical test methods.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to ISO 21881:2019 or kindly contact:

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