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STN	**Skúšobná metóda na posúdenie retencie baktérií v aerosóloch prúdu vzduchu na aplikačných zariadeniach (ISO 24072: 2023)**	**STN EN ISO 24072** 85 6270

Aerosol bacterial retention test method for air-inlet on administration devices (ISO 24072:2023)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/23

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 24072

July 2023

ICS 11.040.20

English Version

Aerosol bacterial retention test method for air-inlet on administration devices (ISO 24072:2023)

Méthode d'essai de rétention bactérienne dans les aérosols pour les filtres d'admission d'air utilisés sur les dispositifs d'administration (ISO 24072:2023)

Prüfverfahren für die Aerosol-Bakterienrückhaltung beim Lufteinlass an Verabreichungsgeräten (ISO 24072:2023)

This European Standard was approved by CEN on 4 April 2023.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (EN ISO 24072:2023) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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Endorsement notice

The text of ISO 24072:2023 has been approved by CEN as EN ISO 24072:2023 without any modification.

INTERNATIONAL STANDARD

ISO 24072

First edition
2023-06

Aerosol bacterial retention test method for air-inlet filter on administration devices

Méthode d'essai de rétention bactérienne dans les aérosols pour les filtres d'admission d'air utilisés sur les dispositifs d'administration

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

Several methods are used to assess the retention ability of filter membranes, including the liquid bacterial retention test (e.g. ASTM F838-20[1]), the aerosol bacterial retention test (e.g. ASTM F2101-19[2]) and the liquid virus retention test (e.g. ASTM F1671-22[3]). The choice of test method depends on the characteristics of the filtered object. For liquid filters, liquid bacteria retention test is generally adapted. For air filters, the aerosol form of microorganisms is generally used, which is more representative of clinical use.

Since the aerosol bacterial retention test is a destructive test with more stringent requirements for test conditions and personnel operation, its application for routine quality controls is generally not viable.

INTERNATIONAL STANDARD ISO 24072:2023(E)

Aerosol bacterial retention test method for air-inlet filter on administration devices

1 Scope

This document specifies a test method to assess bacterial retention ability of finished stand-alone and integrated air-inlet filters on administration devices for infusion and transfusion applications.

2 Normative references

There are no normative references in this document.