ISO/FDIS 5371

2025-03-0

ISO/FDIS 5371:2025(en)

ISO/TC 142

Secretariat: UNI

Date: 2025-04-14

Containment high efficiency filtration unit (CHEFU) in ventilation system of biosafety facilities

 $Unit\'es \ de \ filtration \ \grave{a} \ tr\`es \ haute \ efficacit\'e \ de \ confinement \ (CHEFU) \ dans \ le \ syst\`eme \ de \ ventilation \ des \ installations \ de \ bios\'ecurit\'e$

iTeh Standards (https://standards.iteh.ai) Document Preview

FDIS stage

https://standards.iteh.ai/catalog/standards/iso/7580dd43-aa66-473b-bf3a-7af32c5e9b28/iso-fdis-5371

Edited DIS - MUST BE USED FOR FINAL DRAFT

ISO/DISFDIS 5371:2025(en)

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: + 41 22 749 01 11 EmailE-mail: copyright@iso.org Website: www.iso.orgwww.iso.org

Published in Switzerland

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/FDIS 5371

https://standards.iteh.ai/catalog/standards/iso/7580dd43-aa66-473h-hf3a-7af32c5e9h28/iso-fdis-5371

ISO/FDIS 5371:2025(en)

Contents

Forev	vord	iv	
Intro	duction	v	
1	Scope	1	
2	Normative references	1	
3	Terms and definitions	1	
4	Design and construction	. 3	
5 5.1 5.2	Requirements	. 3	
5.3	Vacuum deformation test		
5.4 5.5 5.6 5.7	Air tightness Leakage test of the installed HEPA filter Decontamination Leakage identification	. 4 . 4	
6 6.1 6.2 6.3 6.4 6.5 6.6	Test methods	5 5 5 6 6	
7 7.1 7.2 7.3 7.4 7.5	Recommended test timeline	10 10 11 11	
8	Marking	12	
Annex A (normative) Air tightness test method1		13	
Annex B (normative) Method for aerosol concentration uniformity test17			
Anne	x C (informative) Method and examples for CHEFU decontamination methodology verification	21	
Bibliography26			

Edited DIS MUST BE USED FOR FINAL

© ISO <u>2024-2025</u> - All rights reserved ifi

ISO/DISFDIS 5371:2025(en)

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 142, Cleaning equipment for air and other gases.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

https://standards.iteh.ai/catalog/standards/iso/7580dd43-aa66-473h-hf3a-7af32c5e9h28/iso-fdis-5371

ISO/FDIS 5371:2025(en)

Introduction

In laboratories and facilities dealing with critical or hazardous biological materials, such as biosafety laboratories, vaccine manufacturing facilities and animal laboratory facilities, the removal of airborne bioaerosols in the facilities that are released to the surrounding environment is always a major concern. In general, containment high efficiency filtration units (CHEFU) are used for such purpose. When installed in the terminal outlet within the room, the required maintenance such as the decontamination and replacement of filters, are performed in the containment room, e.g. the high-level biosafety lab. When installed in the ventilation duct, all maintenance activities can be performed in the low-risk servicing area and a special design for in situ decontamination or containment filter replacement measures needs to be put in place. This document provides suppliers and users with basic performance requirements and test methods to validate the performance of the devices.

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/FDIS 5371

https://standards.iteh.ai/catalog/standards/iso/7580dd43-aa66-473b-bt3a-7at32c5e9b28/iso-tdis-5371



© ISO 2024-2025 - All rights reserved