

FINAL DRAFT International Standard

ISO/FDIS 5371

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

Unités de filtration à très haute efficacité de confinement (CHEFU) dans le système de ventilation des installations de biosécurité

SO/FDIS 5371

https://standards.iteh.ai/catalog/standards/iso/7580dd43-aa66-

ISO/TC 142

Secretariat: UNI

Voting begins on: **2025-04-28**

Voting terminates on: 2025-06-23

73b-bt3a-7at32c5e9b28/iso-tdis-5371

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

ISO/FDIS 5371:2025(en)

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

ISO/FDIS 5371

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



COPYRIGHT PROTECTED DOCUMENT

© 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 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

ISO/FDIS 5371:2025(en)

Con	tents	Page
Forew	vord	iv
Introd	duction	v
1	Scope	1
2	Normative references	
3	Terms and definitions	
4	Design and construction	
5	Requirements 5.1 Appearance 5.2 Resistance to air flow 5.3 Vacuum deformation test 5.4 Air tightness 5.5 Leakage test of the installed HEPA filter 5.6 Decontamination	3 3 4 4 4
6	Test methods 6.1 Appearance 6.2 Resistance to air flow 6.3 Vacuum deformation test 6.4 Air tightness 6.5 Leakage test of the installed HEPA filter 6.5.1 Test aerosol 6.5.2 Test apparatus 6.5.3 Scanning leak test 6.5.4 Total penetration leakage test 6.6 Decontamination 6.7 Leakage identification	4 5 5 5 5 6 6
7 http	Recommended test timeline 7.1 General ISO/FDIS 5371 7.2 tan Design verification test dards/iso/7580dd43-aa66-473b-bf3a-7af32c5e9b28/iso-fdis-53 7.3 Factory test 7.4 In situ test 7.5 Evaluation of the test results	10 710 10 10
8	Marking	
	x A (normative) Air tightness test method	
Annex	x B (normative) Method for aerosol concentration uniformity test	15
Annex	x C (informative) Method and examples for CHEFU decontamination methodology verification	17
Riblio	oranhy	21

ISO/FDIS 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.

ISO/FDIS 5371

https://standards.iteh.ai/catalog/standards/iso/7580dd43-aa66-473b-bf3a-7af32c5e9b28/iso-fdis-537