



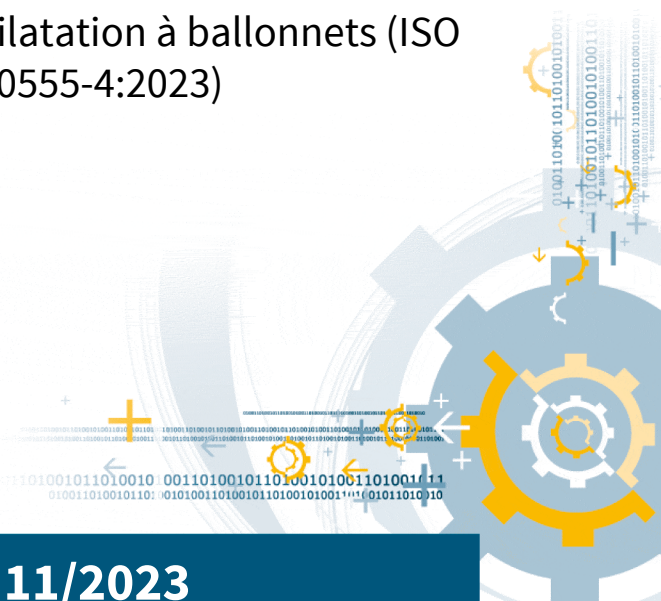
Institut luxembourgeois de la normalisation  
de l'accréditation, de la sécurité et qualité  
des produits et services

## ILNAS-EN ISO 10555-4:2023

### **Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:2023)**

Intravaskuläre Katheter - Sterile Katheter  
zur einmaligen Verwendung - Teil 4:  
Ballondilatationskatheter (ISO  
10555-4:2023)

Cathéters intravasculaires - Cathéters  
stériles et non réutilisables - Partie 4:  
Cathéters de dilatation à ballonnets (ISO  
10555-4:2023)



## National Foreword

This European Standard EN ISO 10555-4:2023 was adopted as Luxembourgish Standard ILNAS-EN ISO 10555-4:2023.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

### **THIS PUBLICATION IS COPYRIGHT PROTECTED**

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

## English Version

## Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:2023)

Cathéters intravasculaires - Cathéters stériles et non  
réutilisables - Partie 4: Cathéters de dilatation à  
ballonnets (ISO 10555-4:2023)

Intravaskuläre Katheter - Sterile Katheter zur  
einmaligen Verwendung - Teil 4:  
Ballondilatationskatheter (ISO 10555-4:2023)

This European Standard was approved by CEN on 24 November 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

Contents	Page
European foreword.....	3

ILNAS-EN ISO 10555-4:2023 - Preview only Copy via ILNAS e-Shop

## European foreword

This document (EN ISO 10555-4:2023) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" 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 May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10555-4:2013.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

## Endorsement notice

The text of ISO 10555-4:2023 has been approved by CEN as EN ISO 10555-4:2023 without any modification.

---

---

# Intravascular catheters — Sterile and single-use catheters —

## Part 4: Balloon dilatation catheters

*Cathéters intravasculaires — Cathéters stériles et non réutilisables —  
Partie 4: Cathéters de dilatation à ballonnets*



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2023

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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Requirements</b> .....	<b>2</b>
4.1 General.....	2
4.2 Detectability of the balloon position .....	2
4.3 Designation of nominal size.....	2
4.4 Physical requirements.....	2
4.4.1 Balloon rated burst pressure (RBP) .....	2
4.4.2 Balloon fatigue; freedom from leakage and damage on inflation .....	2
4.4.3 Balloon deflation time.....	2
4.4.4 Balloon diameter to inflation pressure (balloon compliance) .....	2
4.4.5 Crossing profile .....	3
4.4.6 Balloon removal.....	3
4.5 Information to be supplied with the catheter .....	3
<b>Annex A (normative) Test for rated burst pressure (RBP)</b> .....	<b>4</b>
<b>Annex B (normative) Balloon fatigue test for freedom from leakage and damage on inflation</b> .....	<b>6</b>
<b>Annex C (normative) Test for balloon deflation time</b> .....	<b>8</b>
<b>Annex D (normative) Test for balloon diameter to inflation pressure (balloon compliance)</b> .....	<b>10</b>
<b>Annex E (normative) Determination of crossing profile</b> .....	<b>12</b>
<b>Annex F (normative) Test method for balloon removal</b> .....	<b>14</b>
<b>Annex G (informative) Rationale and guidance</b> .....	<b>16</b>
<b>Bibliography</b> .....	<b>17</b>