DIN EN ISO 10555-1

ICS 11.040.25

Supersedes
DIN EN ISO 10555-1:2013-11

Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements (ISO 10555-1:2013 + Amd 1:2017); English version EN ISO 10555-1:2013 + A1:2017, English translation of DIN EN ISO 10555-1:2018-04

Intravaskuläre Katheter –
Sterile Katheter zur einmaligen Verwendung –
Teil 1: Allgemeine Anforderungen (ISO 10555-1:2013 + Amd 1:2017);
Englische Fassung EN ISO 10555-1:2013 + A1:2017,
Englische Übersetzung von DIN EN ISO 10555-1:2018-04

Cathéters intravasculaires –
Cathéters stériles et non réutilisables –
Partie 1: Exigences générales (ISO 10555-1:2013 + Amd 1:2017);
Version anglaise EN ISO 10555-1:2013 + A1:2017,
Traduction anglaise de DIN EN ISO 10555-1:2018-04

Document comprises 37 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

A comma is used as the decimal marker.

National foreword

This document (EN ISO 10555-1:2013 + A1:2017) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" (Secretariat: DS, Denmark) in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" (Secretariat: DIN, Germany).

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-01-02 AA "Catheters, drainages".

This standard includes Amendment 1 approved by CEN on 2017-12-15.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▌.

The DIN documents corresponding to the international documents referred to in this document are as follows:

ISO 594-1	DIN EN 20594-1
ISO 594-2	DIN EN 1707
ISO 3104	DIN EN ISO 3104
ISO 3105	DIN 51366
ISO 7886-1	DIN EN ISO 7886-1
ISO 10993-1	DIN EN ISO 10993-1
ISO 11135-1	DIN EN ISO 11135-1
ISO 11137-1	DIN EN ISO 11137-1
ISO 11607-1	DIN EN ISO 11607-1
ISO 11607-2	DIN EN ISO 11607-2
ISO 14971	DIN EN ISO 14971
ISO 15223-1	DIN EN ISO 15223-1
ISO 17665-1	DIN EN ISO 17665-1
ISO 80369-1	DIN EN ISO 80369-1
ISO 80369-7	DIN EN ISO 80369-7

Amendments

This standard differs from DIN EN ISO 10555-1:2013-11 as follows:

a) in subclause 4.6 "Peak tensile force", a note has been added;

b) subclause B.3.2 in Annex B, "Method for determining peak tensile force", has been revised;

c) in the German version, the term number for angiographic catheter (3.15) has been corrected;

d) in the German version, in subclause 6.2 i), the sentence in brackets has been corrected.

Previous editions

DIN 13273-5: 1989-11
DIN EN ISO 10555-1: 1996-11, 1999-11, 2004-09, 2009-09, 2013-11
DIN EN ISO 10555-2: 1997-11

National Annex NA
(informative)

Bibliography

DIN 13273-7, *Catheters for medical use — Part 7: Determination of the x-ray attenuation of catheters — Requirements and testing*

DIN 51366, *Testing of mineral oil hydrocarbons — Measurement of kinematic viscosity by means of the Cannon-Fenske viscometer for opaque liquids*

DIN EN 1707, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings*

DIN EN ISO 3104, *Petroleum products — Transparent and opaque liquids — Determination of kinematic viscosity and calculation of dynamic viscosity*

DIN EN ISO 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*[*]

DIN EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

DIN EN ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

DIN EN ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

DIN EN ISO 14971, *Medical devices — Application of risk management to medical devices*

DIN EN ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

DIN EN ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

DIN EN 20594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

DIN EN ISO 80369-1, *Small bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

DIN EN ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*[N*)]

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* National footnote: ISO 7886-1:2017 will be published in spring 2018 as DIN EN ISO 7886-1.

N*) National footnote: ISO 80369-7:2016 replaces ISO 594-1 and ISO 594-2.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1

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English Version

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Cathéters intravasculaires — Cathéters stériles et non réutilisables — Partie 1: Exigences générales (ISO 10555-1:2013 + Amd 1:2017)

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This European Standard was approved by CEN on 29 may 2013. Amendment A1 modifies the European Standard EN ISO 10555-1:2013; it was approved by CEN on 15 December 2017.

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

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