BS EN ISO 7864:2016

BSI Standards Publication

# Sterile hypodermic needles for single use — Requirements and test methods (ISO 7864:2016)

bsi.

**National foreword**

This British Standard is the UK implementation of EN ISO 7864:2016. It supersedes BS EN ISO 7864:1996 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.


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**Compliance with a British Standard cannot confer immunity from legal obligations.**

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 7864

August 2016

ICS 11.040.25

Supersedes EN ISO 7864:1995

English Version

# Sterile hypodermic needles for single use - Requirements and test methods (ISO 7864:2016)

Aiguilles hypodermiques stériles, non réutilisables - Exigences et méthodes d'essai (ISO 7864:2016)

Sterile Injektionskanülen für den Einmalgebrauch - Anforderungen und Prüfverfahren (ISO 7864:2016)

This European Standard was approved by CEN on 15 July 2016.

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.

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**



Ref. No. EN ISO 7864:2016 E

## European foreword

This document (EN ISO 7864:2016) 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 February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

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

This document supersedes EN ISO 7864:1995.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated ISO or IEC standard, as listed in Table 1.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

**Table 1— Correlations between undated normative references and dated EN and ISO standards**

| Normative references as listed in Clause 2 of the ISO standard | Equivalent dated standard | |
|---|---|---|
| | **EN** | **ISO or IEC** |
| ISO 594-1 | EN 20594-1: 1993/AC: 1996/ A1: 1997 | ISO 594-1:1986 |
| ISO 594-2 | EN 1707:1996 | ISO 594-2:1998 |
| ISO 3696 | EN ISO 3696:1995 | ISO 3696:1987 |
| ISO 6009 | EN ISO 6009:1994/AC:2008 | ISO 6009:2016 |
| ISO 8601 | -- | ISO 8601: 2004 |
| ISO 9626 | EN ISO 9626:1995/A1:2001 | ISO 9626:2016 |
| ISO 10993-1 | EN ISO 10993-1:2009 | ISO 10993-1:2009 |
| ISO 14971 | EN ISO 14971:2012 | ISO 14971:2007 |
| ISO 23908 | EN ISO 23908::2013 | ISO 23908:2011 |
| ISO 80369-1 | EN ISO 80369-1:2010 | ISO 80369-1:2010 |
| ISO 15223-1 | EN ISO 15223-1:2012 | ISO 15223-1:2012 |

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 7864:2016 has been approved by CEN as EN ISO 7864:2016 without any modification.

# Annex ZA
(informative)

## Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/295 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 160].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]**

| Essential Requirements of Directive 93/42/EEC | Clause(s)/sub-clause(s) of this EN | Remarks/Notes |
|---|---|---|
| 7.1 | 4.9.1, 4.9.4, 4.14 | |
| 7.3 | 4.4, 4.5, 4.9.1, 4.9.4, 4.14 | |
| 7.5 | 4.4, 4.5, 4.9.1, 4.9.4, 4.14 | The part of ER 7.5 related to phthalates is not explicitly covered. |
| 7.6 | 4.8.1 | |
| 8.1 | 4.14, 5 | The part of ER 8.1 relating to easy handling is not addressed. |
| 8.3 | 5 | |
| 8.4 | 4.14.1, 5.1 | |
| 9.1 | 4.8.1 | |
| 9.2 | 4.6, 4. 9.3, 4.9.4, 4.10 | |

| | | |
|---|---|---|
| 13.1 | 6.1 | |
| 13.2 | 4.7, 4.8.2, 4.9, 6.2, 6.3 | |
| 13.3(a) | 6.2(e), 6.3(g), 6.4(e) | |
| 13.3(b) | 6.2(a), 6.3(a), 6.4(a) | |
| 13.3 (c) | 6.2(b), 6.3(b), 6.4(c) | |
| 13.3(d) | 6.2(c), 6.3(e),6.4(b) | |
| 13.3(e) | 6.2 (f), 6.3(f), 6.4(d) | |
| 13.3 (f) | 6.2(d), 6.3(c) | |
| 13.3(i) | 6.3(h), 6.4(f) | |
| 13.3(k) | 6.1, 6.3(d) | |

**WARNING 1 —** Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2 —** Other Union legislation may be applicable to the products falling within the scope of this standard.

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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.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

In some countries, national regulations are legally binding and their requirements take precedence over the ones in this International Standard.

This fourth edition cancels and replaces the third edition (ISO 7864:1993), which has been technically revised with the following changes:

a) expansion of the range of gauges;

b) introduction of tapered needle designation;

c) reference to the new ISO 80369- series;

d) new informative annex on penetration force;

e) change in Annex B on fragmentation;

f) deleted informative Annex C for symbol for "do-not-reuse" and added normative reference to ISO 15223-1;

g) new informative annex on flow rate;

h) new informative annex on needle bonding strength;

i) reference to ISO 23908 on sharps injury protection.

# Introduction

This International Standard covers sterile hypodermic needles for single use intended to inject or withdraw fluids from primarily the human body.

Plastics materials to be used for the construction of needles are not specified, as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers.

Hypodermic needles specified in this International Standard are intended for use with syringes having a 6 % Luer conical fitting as specified in ISO 80369-7 in conjunction with ISO 80369-1 and ISO 80369-20.

Devices/connectors intended to mate with hypodermic needles of the standard, but which deviate from ISO 80369-7 shall provide demonstrated evidence of safe functional performance.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

# Sterile hypodermic needles for single use — Requirements and test methods

## 1 Scope

This International Standard specifies requirements for sterile hypodermic needles for single use of designated metric sizes 0,18 mm to 1,2 mm.

It does not apply to those devices that are covered by their own standard such as dental needles and pen needles.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-1[1)], *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*

ISO 594-2[2)], *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 6009, *Hypodermic needles for single use Colour coding for identification*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

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

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

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

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

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply:

1) Upon its publication, ISO 80369-7 will replace ISO 594-1.

2) Upon its publication, ISO 80369-7 will replace ISO 594-2.

**3.1**
**gauge**
legacy size designation; a particular gauge size corresponds to a designated metric size defining limits for outer diameters

**3.2**
**unit packaging**
packaging of an individual device, intended to maintain its sterility

**3.3**
**user packaging**
packaging, which contains one or more items of unit packaging, designed to provide labelling information to the user

**3.4**
**needle cap**
cover intended to physically protect the needle tube prior to use

**3.5**
**tapered needle**
needle with conical needle tube which has an outer diameter spanning at least two consecutive designated metric sizes

## 4 Requirements

### 4.1 General

Testing finished products shall be conducted on sterilized products.

### 4.2 Statistics and reproducibility of test methods

Any suitable test system can be used when the required accuracy (calibration) and precision [Gauge repeatability and reproducibility (R&R)] can be obtained.

### 4.3 Cleanliness

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter.

When examined under 2,5× magnification, the hub socket (fluid path surface) shall appear free from particles and extraneous matter.

### 4.4 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Annex A shall be within one unit of pH of that of the control fluid.

### 4.5 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with Annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0,1 mg/l.

## 4.6 Size designation

### 4.6.1 Tubular needle designation

The size of the hypodermic needle shall be designated by the following:

a) the designated metric size of the needle tube, may also be expressed in millimetres

   — considering the regional distribution of the products, optionally the needle size expressed in gauge size;

b) the nominal length of the needle tube, expressed in millimetres (Figure 2);

c) optionally, the wall thickness of the needle, expressed as RW (regular wall), TW (thin wall), ETW (extra thin wall), or UTW (ultra-thin wall).

EXAMPLE 0,8 mm × 40 mm TW.

### 4.6.2 Tapered needle designation

Details necessary for the user to identify the needle, including the designated metric size, shall be provided in accordance with the following expression:

OD (tip)/OD (hub) × L

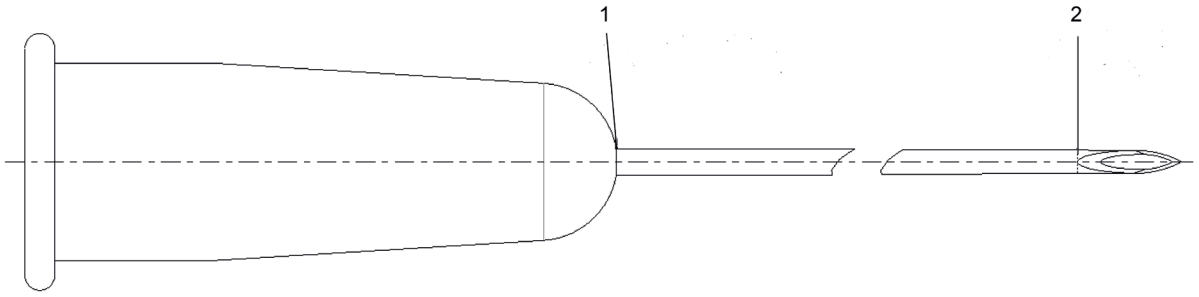
where

OD (tip) is the designated metric size of the needle tube at the first full diameter from the tip (measuring point 2, at the end of the bevel geometry as shown in Figure 1) expressed in millimetres;

OD(hub) is the designated metric size of the needle tube at the hub side, measured at the first full diameter from the top of the hub or from the top of the jointing medium, if used, (measuring point 1 at the end of the hub geometry as shown in Figure 1) expressed in millimetres;

L is the nominal length of the needle tube, expressed in millimetres (Figure 2).

EXAMPLE 0,23 mm/0,25 mm × 6 mm TW.




**Key**

1 OD. (hub)

2 OD. (tip)

**Figure 1 — Tapered needle designation**

## 4.7 Colour coding

The designated metric size of hypodermic tubular needles or the first full diameter from the tip of a tapered needle shall be identified by colour coding in accordance with ISO 6009 applied to the unit packaging and/or part of the needle assembly such as the needle hub or the needle cap.

## 4.8 Needle hub

### 4.8.1 Conical fitting

The conical socket of the hypodermic needle hub shall meet the requirements of ISO 80369-1, ISO 594-1 and ISO 594-2.

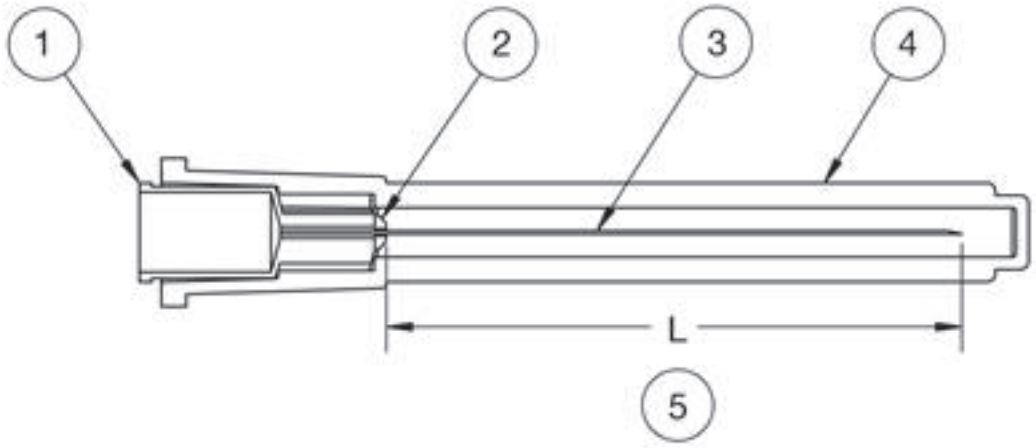
NOTE Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.

### 4.8.2 Colour of hub

The hub shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with ISO 6009.

## 4.9 Needle cap

If a separate needle cap is provided, it shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with ISO 6009.




**Key**

1 hub
2 jointing medium
3 needle tube
4 needle cap
5 length

**Figure 2 — Example of a typical hypodermic needle and needle cap for single use**

NOTE Figure 2 represents a typical configuration of a hypodermic needle. Specific designs can vary based on the packaging design of the manufacturer.

## 4.10 Needle tube

### 4.10.1 General

Needles according to the tubular needle designation shall be in accordance with ISO 9626. For tapered needles, manufacturers shall define how to apply the functional tests specifically stiffness and resistance to breakage on the basis of a specific risk assessment carried out according to ISO 14971.

### 4.10.2 Tolerances on length

The actual length of the needle tube (see dimension L in Figure 2) shall equal the nominal length within the tolerances given in Table 1.

**Table 1 — Tolerances on length of needle tube**

Dimensions in millimetres

| Nominal length of needle tube | Tolerance |
|---|---|
| <25 | +1<br>−2 |
| 25 to 39 | +1,5<br>−2,5 |
| 40 | 0<br>−4 |
| >40 | +1,5<br>−2,5 |

### 4.10.3 Freedom from defects

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the outer surface of the tubing shall be smooth and free from defects.

### 4.10.4 Lubricant

If the hypodermic needle tube is lubricated, the lubricant shall not be visible, under normal or corrected vision, as droplets of fluid on the outer or inner surfaces of the needle tube.

An acceptable lubricant, applied undiluted, is polydimethylsiloxane complying with a national or the European pharmacopoeia. The quantity of lubricant used should not exceed 0,25 mg/cm$^2$ of the lubricated surface area of the needle tube.

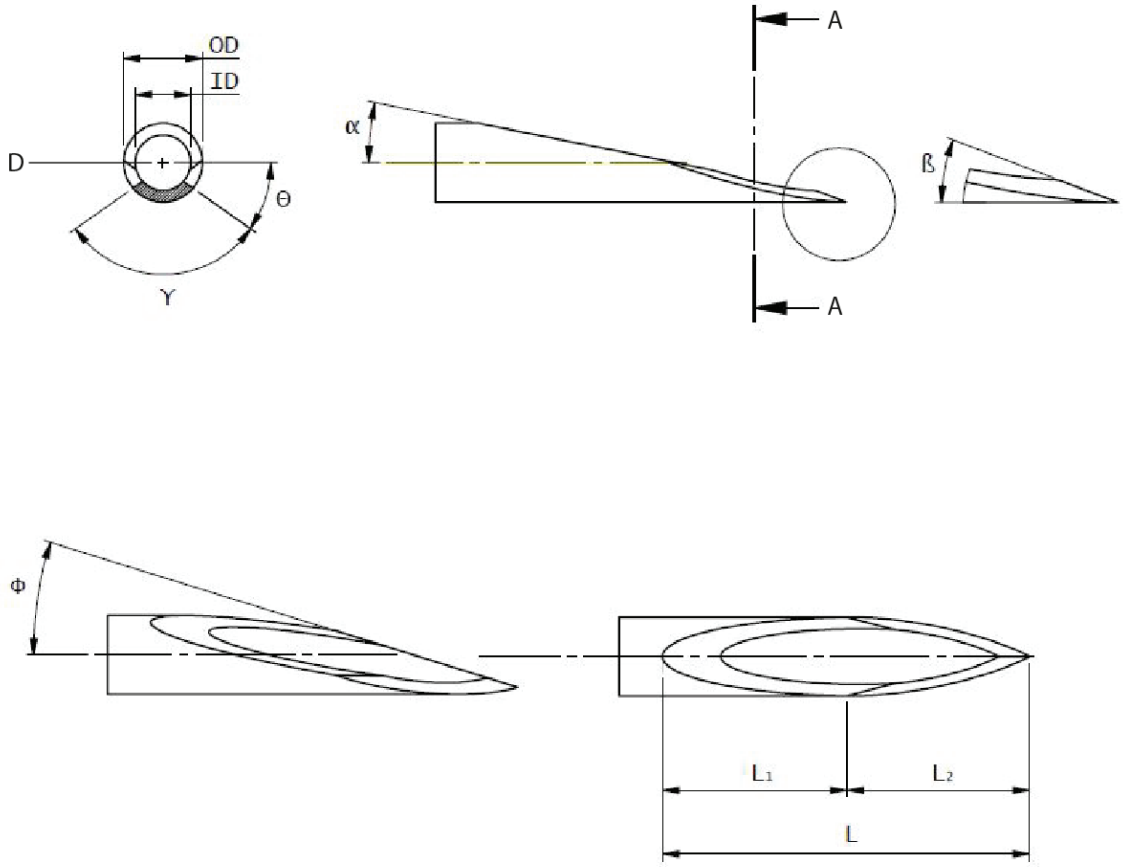
## 4.11 Needle point

When examined under 2,5× magnification the needle point shall appear sharp and free from feather edges, burrs and hooks.

NOTE The needle point usually has a bevel with a primary bevel angle of 11° ± 2° (as illustrated in Figure 3), but a "short" bevel with other angle, e.g. 17° ± 2°, can be provided.

The designation of needle point dimensions and the nomenclature used to describe the dimensions and features is shown for information in Figure 3. The needle points shown are of configurations commonly manufactured: other configurations may be equally satisfactory. It may not be necessary to use all the dimensions when describing the point configuration.

The needle point should be designed so as to minimize coring and fragmentation when penetrating vial closures. This International Standard does not specify requirements or test methods for these properties, but an example of a test method for determining the production of fragments from rubber closures is given in Annex B. Penetration testing can provide an indication of the needle point sharpness and lubrication. An example of a test method for determining the needle penetration performance is given in Annex D.




**Key**

OD outer diameter of needle tube
ID inner diameter of needle tube
L point length
L1 primary bevel length
L2 secondary bevel length
$\alpha$ primary bevel angle
$\phi$ secondary bevel angle when rotated $\theta$
$\beta$ tip angle
$\theta$ secondary bevel rotation angle
$\gamma$ combined secondary bevel rotation angle
D view of section A-A

**Figure 3 — Designation of dimensions and nomenclature of needle point geometry**

## 4.12 Bond between hub and needle tube

The union of the hub and needle tube shall not be broken by the minimum force given in Table 2. when applied as tension in the direction of the needle axis.

For tapered needles, the minimum force given in Table 2 is determined by the outer diameter at the hub [OD. (hub)] as indicated in Figure 1.

An example of a test method for determining needle bonding strength is given in Annex E.

**Table 2 — Force to test bond between hub and needle tube**

| Designated metric size of needle<br>mm | Force<br>min.<br>N |
|---|---|
| 0,18 | 11 |
| 0,2 | 11 |
| 0,23 | 11 |
| 0,25 | 11 |
| 0,3 | 11 |
| 0,33 | 22 |
| 0,36 | 22 |
| 0,4 | 22 |
| 0,45 | 22 |
| 0,5 | 22 |
| 0,55 | 34 |
| 0,6 | 34 |
| 0,7 | 40 |
| 0,8 | 44 |
| 0,9 | 54 |
| 1,1 | 69 |
| 1,2 | 69 |

### 4.13 Patency of lumen

As appropriate, depending on the needle size and geometry of the needle, patency of the lumen shall be determined by either:

a) a stainless steel stylet of the appropriate diameter selected from the diameters given in Table 3 shall pass through the needle;

b) the flow rate of water through the needle shall not be less than 80 % of an unprocessed needle tube of equivalent outer diameter and length having a minimum inner diameter in accordance with ISO 9626 when tested under the same pressure.

   For needles tapered inside, the patency of lumen shall be verified by flow rate measurements. The unprocessed needle tube should have minimum inner diameter at both the tip and hub corresponding to their respective designations from ISO 9626.

An example of an appropriate method to determine flow rate is given in Annex C.

**Table 3 — Size of stylet to test patency of lumen**

Dimensions in millimetres

| Designated metric size of needle | Outer diameter of stylet | | | |
|---|---|---|---|---|
| | for needle of regular walled tubing | for needle of thin-walled tubing | for needle of extra-thin-walled tubing | for needle of ultra-thin-walled tubing |
| 0,30 | 0,11 | 0,13 | 0,15 | 0,19 |
| 0,33 | 0,11 | 0,15 | 0,19 | 0,21 |
| 0,36 | 0,11 | 0,15 | - | - |
| 0,4 | 0,15 | 0,19 | - | - |
| 0,45 | 0,18 | 0,23 | - | - |
| 0,5 | 0,18 | 0,23 | - | - |
| 0,55 | 0,22 | 0,27 | - | - |
| 0,6 | 0,25 | 0,29 | 0,30 | - |
| 0,7 | 0,30 | 0,35 | 0,37 | - |
| 0,8 | 0,40 | 0,42 | 0,44 | - |
| 0,9 | 0,48 | 0,49 | 0,50 | - |
| 1,1 | 0,58 | 0,60 | 0,68 | - |
| 1,2 | 0,70 | 0,73 | 0,83 | - |

It is recommended to use method b) for needles below 0,30 mm and hence no stylets are listed in Table 3 for designated metric sizes below 0,30 mm.

### 4.14 Sharps injury protection

The needle shall meet the requirements of ISO 23908 when an integrated sharps protection feature is provided.

### 4.15 Sterility and biocompatibility

#### 4.15.1 Sterility

The needle in its unit packaging shall have been subjected to a validated sterilization process resulting in a Sterility Assurance Level of at least $10^{-6}$ in accordance with recognized ISO standards.

#### 4.15.2 Biocompatibility

The needle shall be free from biological hazard in accordance with the requirements of ISO 10993-1.

## 5 Packaging

### 5.1 Unit packaging

Each hypodermic needle shall be sealed in a unit package. The material and design of this packaging shall be such as to ensure that the colour coding of the contents is visible.

The materials of the packaging shall not have detrimental effects on the contents. The materials and design of this container shall be such as to ensure:

a) the maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) the minimum risk of contamination of the contents during removal from the container;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the container cannot be easily resealed, and it shall be obvious that the container has been opened.

### 5.2 User packaging

Multiple items of unit packaging shall be packed in a user packaging.

User packaging shall be sufficiently robust to protect the contents during handling, transit and storage.

Multiple items of user packaging may be packaged in a storage and/or a transit container.

## 6 Information supplied by the manufacturer

### 6.1 General

The needle shall be accompanied by the information that is sufficient for its safe use, taking account of the training and knowledge of potential users. However, for general application hypodermic needles, it is recognized that no instructions for use are supplied. The information shall include the identity of the manufacturer.

### 6.2 Unit packaging

The unit packaging shall be marked with at least the following information:

a) a description of the contents, including the designated metric size in accordance with 4.6;

b) the word “STERILE” or equivalent, such as symbol for ”Sterile”, ISO 15223-1;

NOTE See ISO 15223-1:2012, symbol number 5.2.1 or symbol number 5.2.2 to 5.2.5 indicating the sterilization method accordingly.

c) an identification reference to the batch code or lot number, prefixed by the symbol for “Batch code“ from ISO 15223-1 or the word “LOT”;

NOTE See ISO 15223-1:2012, symbol number 5.1.5.

d) the words “FOR SINGLE USE” or equivalent such as symbol for ”Do not reuse”, ISO 15223-1. The term “disposable“ shall not be used;

NOTE See ISO 15223-1:2012, symbol number 5.4.2.

e) the name and/or tradename of the manufacturer and, where applicable, reference to its authorized representative;

f) the expiry date, if required, prefixed by the ISO 15223-1 symbol “Use-by date”. This symbol shall be accompanied by a date to indicate that the needle should not be used after the end of the year and month. The date shall be expressed as in ISO 8601 as four digits for the year and two digits for the month, YYYY-MM.

NOTE See ISO 15223-1:2012, symbol number 5.1.4.

### 6.3 User packaging

The user packaging shall be marked with at least the following information:

a) description of the contents, including the designated metric size in accordance with 4.6;

NOTE A description of the contents, including the designated metric size in accordance with 4.6, the quantity, the type or angle of bevel (see NOTE in 4.11) and optionally, the words "regular-walled", or "thin-walled", or "extra-thin-walled", or "ultra-thin-walled" or equivalent or an abbreviation such as RW, TW, ETW, or UTW respectively.

b) the word "STERILE" or equivalent, such as symbol for "Sterile", ISO 15223-1;

NOTE See ISO 15223-1:2012, symbol number 5.2.1 or symbol number 5.2.2 to 5.2.5 indicating the sterilization method accordingly.

c) the words "FOR SINGLE USE" or equivalent such as symbol for "Do not reuse", ISO 15223-1. The term "disposable" shall not be used;

NOTE See ISO 15223-1:2012, symbol number 5.4.2.

d) a warning to check the integrity of each unit packaging before use;

NOTE See ISO 15223-1:2012, symbol number 5.2.8.

e) an identification reference to the batch code or lot number, prefixed by the symbol for "Batch code" from ISO 15223-1 or the word "LOT";

NOTE See ISO 15223-1:2012, symbol number 5.1.5.

f) the expiry date, if required, prefixed by the ISO 15223-1 symbol "Use-by date". This symbol shall be accompanied by a date to indicate that the needle should not be used after the end of the year and month. The date shall be expressed as in ISO 8601 as four digits for the year and two digits for the month, YYYY-MM.

NOTE See ISO 15223-1:2012, symbol number 5.1.4.

g) the name and/or tradename and the address of the manufacturer and, where applicable, reference to its authorized representative;

h) information on handling, storage and transportation if no storage container is used for transportation.

## 6.4 Storage container

If user packaging is packaged in a storage container, the storage container shall be marked with at least the following information:

a) a description of the contents as specified in 6.2 a);

b) an identification reference to the batch code or lot number, prefixed by the symbol for "Batch code" from ISO 15223-1 or the word "LOT";

NOTE See ISO 15223-1:2012, symbol number 5.1.5.

c) the word "STERILE" or equivalent, such as symbol for "Sterile", ISO 15223-1;

NOTE See ISO 15223-1:2012, symbol number 5.2.1 or symbol number 5.2.2 – 5.2.5 indicating the sterilization method accordingly.

d) the expiry date, if required, prefixed by the ISO 15223-1 symbol "Use-by date". This symbol shall be accompanied by a date to indicate that the needle should not be used after the end of the year and month. The date shall be expressed as in ISO 8601 as four digits for the year and two digits for the month, YYYY-MM.

NOTE See ISO 15223-1:2012, symbol number 5.1.4.

e) the name and/or tradename and the address of the manufacturer and, where applicable, reference to its authorized representative;

f) information for handling, storage and transportation of the contents.

## 6.5 Transport wrapping

If a storage container is not used but the secondary containers are wrapped for transportation, the information required by 6.4 shall either be marked on the wrapping or shall be visible through the wrapping.

# Annex A
(normative)

# Method for preparation of extracts

## A.1 Principle

The assembled needle, including the inner surfaces of the needle tube, is immersed in water in order to extract soluble components.

## A.2 Apparatus and reagents

**A.2.1** Freshly distilled or deionized water, of grade 3 in accordance with ISO 3696.

**A.2.2** Selection of laboratory borosilicate glassware.

## A.3 Procedure

**A.3.1** Immerse 25 needles in 250 ml of water (A.2.1) in a suitable container made from borosilicate glass (A.2.2). Ensure that all surfaces of the needles, including the inner of the needle tube, are in contact with the water. Maintain the water at a temperature of $\left(37^{+3}_{0}\right)$ °C for (60 ± 2) min. Remove the needles and ensure that all water from the inner and outer surfaces of the needles is returned to the container.

**A.3.2** Prepare the control fluid by following the procedure given in A.3.1 but omitting the needles.

# Annex B
(informative)

# Fragmentation test for medical needles

## B.1 General

Many medical devices for single use are equipped with penetration parts. These parts are designed for penetrating rubber membranes. Thereby fragments can occur.

Fragments are unintendedly produced particles from rubber during penetration with a penetration part.

The following test method is valid as reference method for elastomeric closure parts (injection stoppers), which are designed for penetration with needles as well as for needles, which are designed for penetration of injection stoppers.

NOTE This test does not include the use of penetration parts for infusion closures.

## B.2 Principle

Penetration of the injection stoppers on injection bottles with a needle. Collecting and counting of the fragments, which occurred from the penetrations.

## B.3 Apparatus and reagents

**B.3.1 25 pcs. injection bottles**, half filled with water and closed with stopper and crimp cap.

**B.3.2 5 pcs. devices for holding and cleaning of the needles**, i.e. syringes for single use.

## B.4 Test parts and injection stoppers

**Table B.1 — Test parts and injection stoppers**

| Test parts | Injection stoppers | |
|---|---|---|
| | Type | Requirements |
| 25 pcs.<br>Hypodermic needles | Injection stoppers<br>ISO 8362-2-20-A | Hardness: 40 to 55 Shore A |

## B.5 Preconditioning

**B.5.1** The needles are used without preconditioning. The injection stoppers are sterilized and dried. Sterilization is done by autoclaving with (121 ± 2) °C for 30 min.

**B.5.2** Drying of the autoclaved stoppers is done at 60°C for 60 min in a drying oven.

**B.5.3** The injection bottles are cleaned to contain no particles, which would give wrong test results.

## B.6 Procedure

**B.6.1** The injection stoppers are assembled on injection bottles, which are half filled with particle free water and fixed with a crimp cap.

**B.6.2** Every stopper is penetrated four times at different locations of the penetration area with a cannula. After the fourth penetration, every cannula is cleaned by pressing through about 1 ml of water into an injection bottle. After 100 penetrations overall, the bottles are opened and the contents filtered with a filter membrane of 0,8 µm.

4 penetrations per cannula x 25 cannulae = 100 penetrations.

## B.7 Test analysis

**B.7.1** Relevant are fragments, which are visible with naked eye from a distance of 25 cm.

**B.7.2** The number of fragments per 100 penetrations is documented.

NOTE For filtration of the water and collection of the particles filters with pore size of 0,8 µm are requested. This size is taken from ISO 8871 (all parts) and PharmEur. For this test filters with pore sizes up to 20 µm can be used, as the evaluation of the particles is done with normal or to normal corrected vision.

# Annex C
(informative)

# Determination of flow rate through the needle

## C.1 Principle

The water flow through a sample needle is measured using an appropriate calibrated and qualified flow meter, or an apparatus such as the one outlined in Figure C.1, combined with a calibrated scale.

## C.2 Reagent

**C.2.1 Distilled water**.

## C.3 Apparatus

**C.3.1 Test fixture**, upon which the sample needle is mounted.

**C.3.2 Water tank**, to which the test fixture is connected, pressurized using compressed air to (1,10 ± 0, 01) bar for needle sizes below 0,6 mm OD and (0,11 ± 0,01) bar for needle sizes equal or larger than 0,6 mm OD.

NOTE Reduction of pressure for diameters equal or larger than 0,6 mm is to ensure laminar flow during the test. The pressure 1,10 bar is considered to best mimic the average user situation.

## C.4 Test procedure

Fill the water tank with water at (23 ± 2) °C and connect or screw the test needle into the test fixture that is connected to the water tank.

The water flows through the needle for at least (15 ± 0,25) s and the efflux is collected in a suitable vessel.

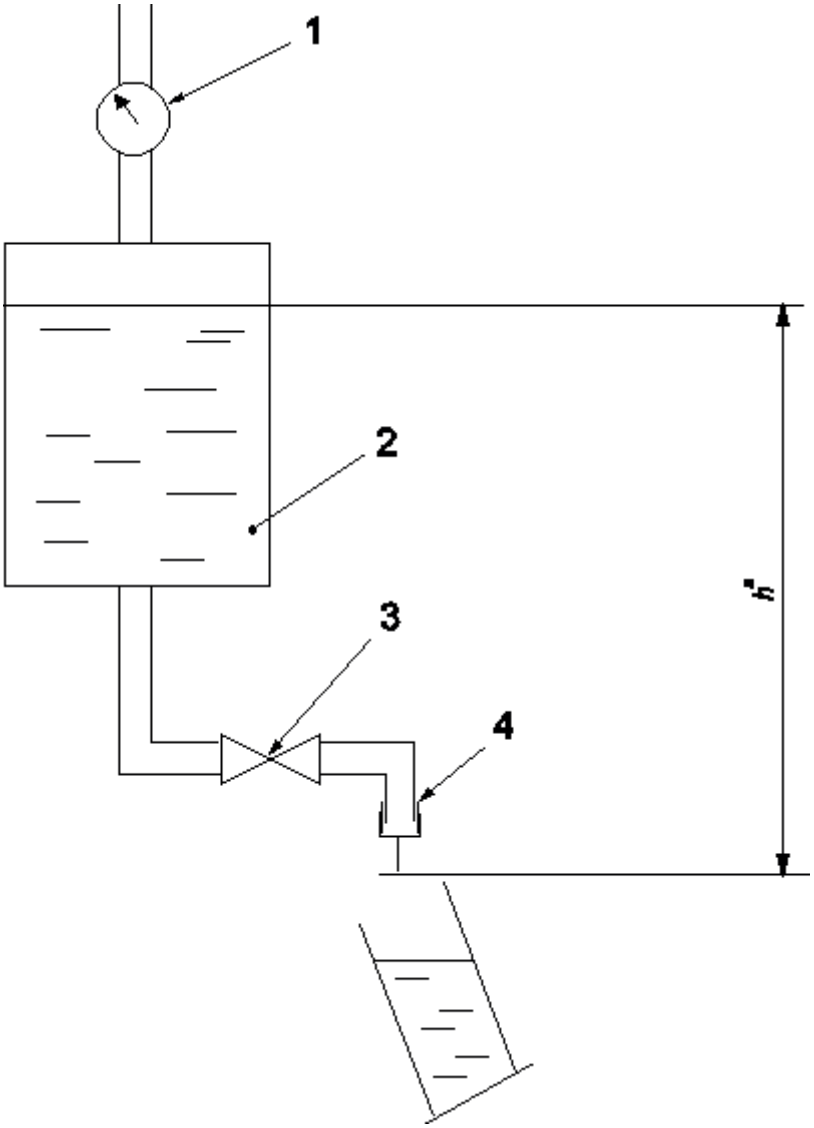
The volume is then determined by weighing with an analytical balance with an accuracy of ±0,001 g, assuming that the density of water equals to 1,0 g/ml.

NOTE The tolerances on temperature, pressure and time keeping have been chosen taking into account what is commonly achieved, although it is recognized that they contribute differently to the overall tolerance.

One test run contains 20 sample needles from three batches.

## C.5 Test analysis

Calculate the nominal flow rate expected through the needle, in millilitres per minute. Calculate the arithmetic average and standard deviation. Water temperature in the flow path shall not reach more than 25 °C.




**Key**

1 pressure gauge
2 distilled water
3 ON/OFF valve
4 needle interface
h[a] Maximum 100 mm.

**Figure C.1 — Example of test equipment**

# Annex D
(informative)

# Test method for measuring the penetration force and drag force for needles

## D.1 Principle

The needle to be tested is inserted into a specific substrate at a specific constant speed and the force for insertion is recorded as a function of penetration depth. A force gage, such as a load cell, is utilized to measure force during different stages of insertion. The needle is inserted to assess both the initial penetration force and the friction force that is required to keep the needle moving through the substrate. Following the forward motion, the needle is removed and the overall force profile is registered.

## D.2 Apparatus and equipment

### D.2.1 Force measurement apparatus.

A force measurement apparatus with a load cell appropriate to the force measurement should be used. The force measurement apparatus should also be capable of holding a needle to be tested and moving it forward and backward at an appropriate test speed.

NOTE A typical test speed selected for needle penetration is 100 mm/min.

### D.2.2 Substrate for insertion testing.

An appropriate substrate shall be selected for the purpose of this test. Substrate shall be validated for the intended use of the test scope and verify reproducibility of test results.

NOTE Some typical test substrates that are currently available include the following:

a) A Natural Latex Rubber substrate, having a hardness of (40 ± 5) Shore A and a nominal thickness of (1,0 ± 0,1) mm.

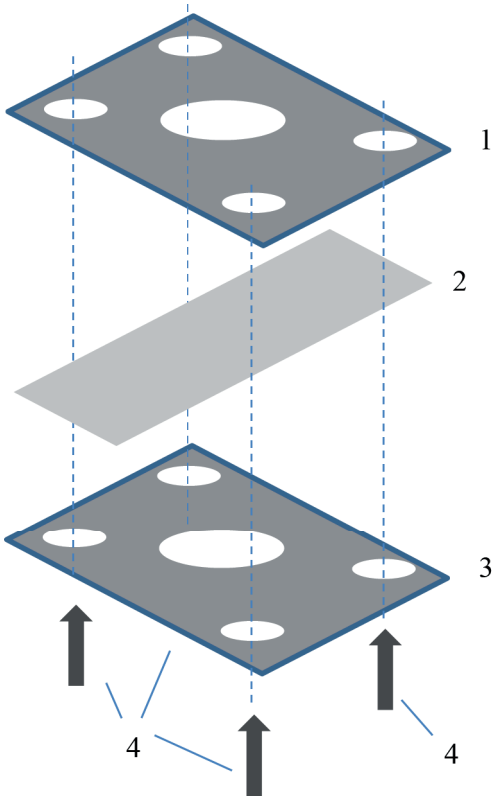
b) A polyurethane substrate having a hardness of (85 ± 10) Shore A and a nominal thickness of (0,40 ± 0,05) mm.

c) Silicone rubber having a hardness of (50 ± 5) Shore A and a nominal thickness of (0,50 ± 0,05) mm.

d) Polyethylene (LDPE) having a thickness of (50 ± 5) microns and Young's modulus of (130 ± 10) MPa.

### D.2.3 Substrate holder.

The holder should consist of two parallel plates capable of securely holding a sheet of substrate between them. A circular open penetration area, having a nominal diameter of 10 mm, should be available to do the insertion testing. The holder should be designed such that the compressive force between the parallel plates is the same for all the samples. An example of a design for the holder is shown in Figure D.1 below. The schematic shows parallel plates held together with sufficient and consistent compressive force to prevent movement of the substrate.




**Key**

1 top plate
2 substrate strip
3 bottom plate
4 spring loaded screws

**Figure D.1 — Schematic of an example of substrate holder and compression mechanism**

### D.2.4 Penetration depth.

The needle should be inserted into the substrate for a penetration depth equivalent of 80 % of the nominal length. For example, a 5 mm needle should be inserted 4 mm (80 % of 5 mm) into the substrate during the testing. A new substrate site should be used for each penetration test.

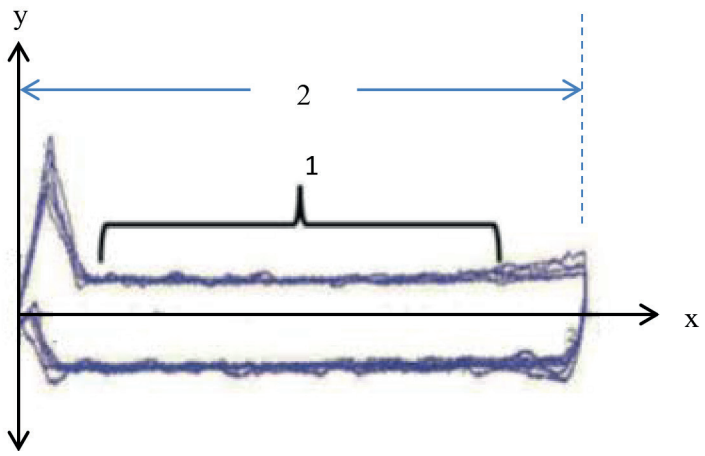
## D.3 Collection and data analysis

A statistically significant sample size should be chosen depending on the objective of the test.

Two main outputs should be measured using the force profile.

a) Peak penetration force - the maximum force required to insert needle into the securely held substrate at the defined speed. This force corresponds to the maximum force value in the force profile.

b) Drag force - the average “friction” force obtained from a representative portion of the force profile. The average drag force should be calculated using up to 80 % of the penetration depth. The average force thus calculated represents the drag force for that specific sample tested. An example of a typical force profile when a latex substrate is used for penetration testing, and the region from which drag force should be obtained is shown in Figure D.2 below.

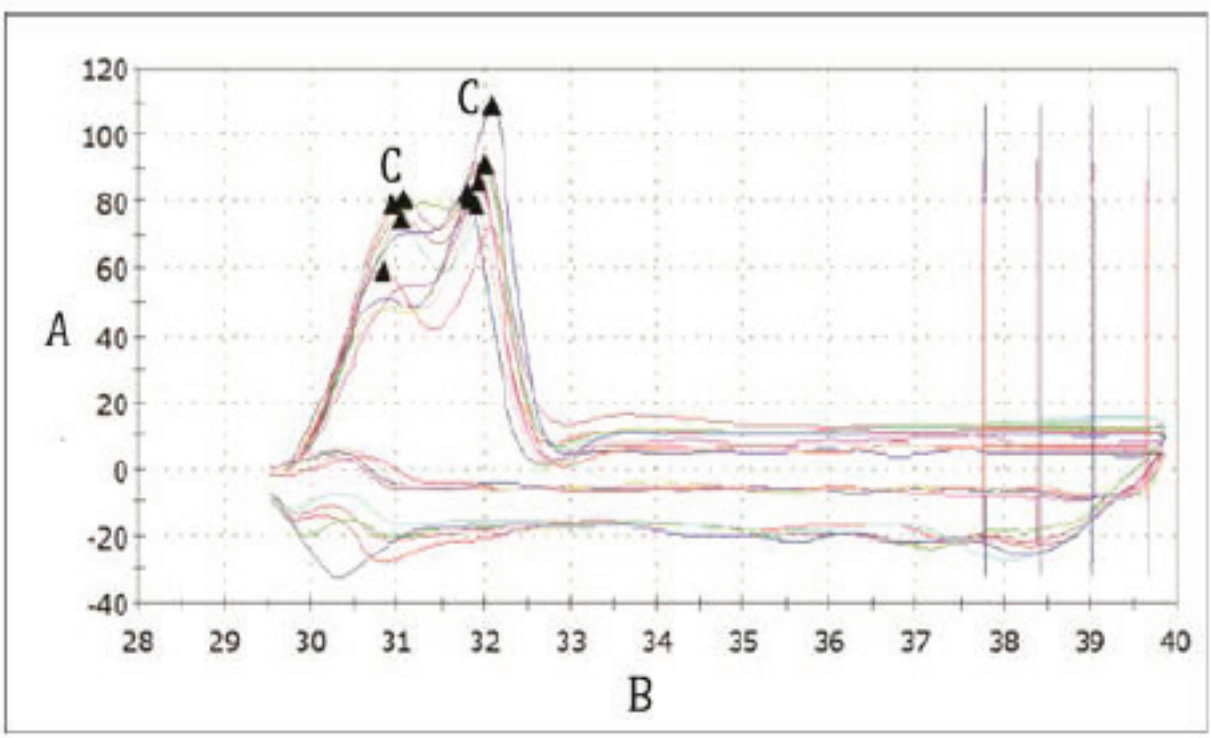



**Key**

1 drag force region
2 penetration depth
x displacement
y force

**Figure D.2 — Example of force profile obtained from a latex substrate and the region of the force profile from which drag force is calculated**

NOTE 1 Also shown is the unique value of peak penetration force obtained from each force profile.




**Key**

A compressive load (gf)
B compressive extension (mm)
C multiple peaks resulting from different cutting edges of the needle

**Figure D.3 — Example of force profile obtained from a polyurethane substrate**

NOTE 2 As shown in the figure, polyurethane substrate gives multiple peaks corresponding to different cutting edges of the needle

## D.4 Procedure

Before testing, the test samples and the test substrate shall be stored at least 24 h at standard ambient laboratory conditions. Test shall be performed at standard ambient laboratory conditions:

— temperature from 18 °C to 28 °C;

— relative humidity from 25 %RH to 75 %RH;

— the needle should be mounted onto the force measurement apparatus;

— the substrate should be secured inside the substrate holder, such that it is visible in the target penetration area;

— the axis of motion of the needle is aligned perpendicular with the circular target area for substrate insertion;

— the needle should be then moved towards the substrate at the prescribed speed such that the substrate is penetrated and the desired penetration depth is obtained;

— the needle should be retracted from the substrate to complete the testing;

— if the needle collides with the substrate holder due to misalignment of the needle axis with the target penetration area, the sample should be discarded and a replacement sample should be tested;

— calculate the drag force as explained in D.3 b);

— the mean and standard deviation of the two outputs should be calculated based upon the predetermined sample size.

## D.5 Test report

The test report should include the mean and standard deviation for the two outputs mentioned above: Peak Penetration Force and Drag Force.

# Annex E
(informative)

# Needle bonding strength test method

## E.1 Principle

The test is used to assess the bonding strength between the needle tube and the needle hub.

It is mainly designed to verify whether the applied needle bonding system is appropriate for the needle to withstand a tensile force as determined by the designated metric size of the needle.

## E.2 Materials

**E.2.1** Sterilized hypodermic needles, sample size as determined for the intended test program.

## E.3 Apparatus

**E.3.1** Universal tensile and compression testing machine complying with the following:

— load cell of max 500 N or as appropriate for the force to be measured;

— test speed of 50 mm/min (or as appropriate depending on the intended method and application);

— sampling rate as appropriate for this testing purpose.

**E.3.2** Needle hub holder allowing the needle to be aligned with the lower gripper.

**E.3.3** Needle tube gripper device with gripper jaws designed to avoid slippage, but at the same time not influencing the measurement outcome itself (pinching the needle tube).

## E.4 Preparation and preservation of test samples

Testing is made at ambient laboratory conditions, unless otherwise specified.

## E.5 Procedure

**E.5.1** Insert the test sample vertically positioned on the testing machine.

**E.5.2** Grip the needle in such a manner to avoid slippage.

**E.5.3** Set the load cell to “zero”. Ensure that no significant pre-load is applied when the “Zero” is set.

**E.5.4** Apply a test speed of 50 mm/min or as appropriate at an appropriate sampling rate [Hz].

**E.5.5** Start the test.

**E.5.6** Record the maximum force.

**E.5.7** Stop the test once the needle is clearly removed from the hub, or the hub or needle tube is broken.

## E.6 Expression of results

Record the maximum load (N). This corresponds to the needle bonding force.

## E.7 Test report

The test report shall include the following:

— the test speed (mm/min);

— the sampling rate (Hz);

— the peak value according to the maximum force (N);

— the number of tested samples.

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3) To be published.

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