INTERNATIONAL STANDARD

ISO 17218

First edition
2014-02-01

Sterile acupuncture needles for single use

Aiguilles d'acupuncture stériles à usage unique

Reference number
ISO 17218:2014(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 249, *Traditional Chinese medicine.*

Introduction

This International Standard applies to sterile acupuncture needles for single use (specialized for filiform needles) used by professional acupuncturists for acupuncture treatment. Sterile acupuncture needles for single use are sterilized by the manufacturer, and the healthcare professional can open the sealed package and use the needle immediately.

In order to encourage innovation, this International Standard does not enforce the combination of the needle diameter and length. However, considering the clinical usage requirements, the standard provides the specifications for the needle diameter and length.

The sharpness and puncture performance of the needle tip are of very important clinical significance. Annex A states the guidelines and the evaluation methods for the intensity and the sharpness of the needle tip, while Annex B provides two qualitative and quantitative evaluation methods to determine the puncture performance of the needle tip.

The qualitative methods to evaluate the puncture performance of needle tip are described in Annex B. The methods are simple, direct and practical. It makes them especially suitable for routine inspection and for cross-comparison of the acupuncture needles' clinical applications. They also play a very important role in the enhancement of the quality of the needle tip. The methods to evaluate the puncture performance of the needle tip can be used to further evaluate the puncture and puncture performance of the acupuncture needle. Currently, the more appropriate method is to use the needle tip to pierce through polyurethane material; however, this method has not yet been implemented internationally.

Considering the consistency of standards in the future, this standard provides the methods to evaluate the puncture performance of the needle tip and ranks 5.3.5.2 as recommended. The standard does not provide the sharpness index of the piercing through polyurethane material by the needle tip. This index will be added to the standard when it becomes appropriate. To improve product quality, all inspection reports should include the inspection information as well as the results of the performance evaluation.

Since every manufacturer's design, production, and sterilization methods are different, no regulations exist for the materials of the acupuncture needle handle. Still, the needle body and the needle handle of acupuncture needle should have good biocompatibility.

In order to ensure product safety and efficacy, the manufacturer should perform risk analysis and enforce risk management in addition to adhering to the requirements of local rules and regulations, the relevant background data of the medical devices and clinical practice throughout the entire duration of the product's life cycle. ISO 14971 has provided manufacturers a framework for the effective management of hazards associated with the use of medical devices.

In some countries, the requirements proposed here are subject to legal sanctions. Such rules and regulations should take precedence over the standards set forth in this document.

Sterile acupuncture needles for single use

1 Scope

This International Standard specifies the requirements for the sterile acupuncture needles for single use (specialized for filiform 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 6507-1:2005, *Metallic materials — Vickers hardness test — Part 1: Test method*

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

ISO 15223-1, *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.

3.1
body of the needle
part of the acupuncture needle that is inserted into the human body

Note 1 to entry: See Figure 1.

3.2
handle of the needle
part of the acupuncture needle that is not inserted into the human body

Note 1 to entry: See Figure 1.

3.3
tip of the needle
sharp apex at the end of the acupuncture needle body that is inserted into the human body

Note 1 to entry: See Figure 1.

3.4
root of the needle
part of the acupuncture needle that connects the needle body to the needle handle

Note 1 to entry: See Figure 1.

3.5
tail of the needle
end part of the needle handle at the opposite side of the tip of the needle

Note 1 to entry: See Figure 1.

3.6
sterile acupuncture needle
acupuncture needle that has been sterilized

3.7
guide tube
assistant tool in the shape of a slender, long tube into which the needle is placed and used for easy insertion

3.8
hardness of the needle body
measure of resistance of the acupuncture needle body to permanent deformation

3.9
primary package
sealed or closed packaging system that forms a microbial barrier, directly enclosing the acupuncture needle

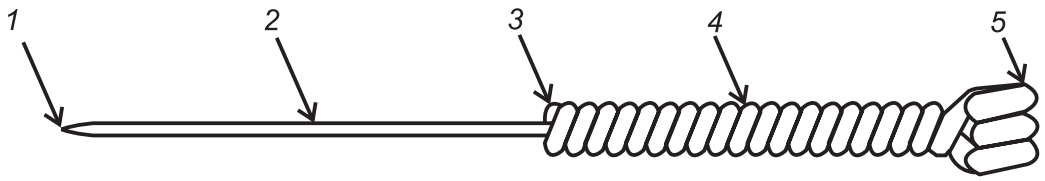
Note 1 to entry: The primary package is usually the smallest unit package of use and the package that is in direct contact with one or more acupuncture needles.

3.10
secondary package
package containing one or more primary packages for distribution and storage

4 Configuration

4.1 Acupuncture needle configuration

The configuration of the acupuncture needle and the name of each of its parts are shown in Figure 1.



Key
1 tip of the needle
2 body of the needle
3 root of the needle
4 handle of the needle
5 tail of the needle

Figure 1 — Example of typical structure of acupuncture needle

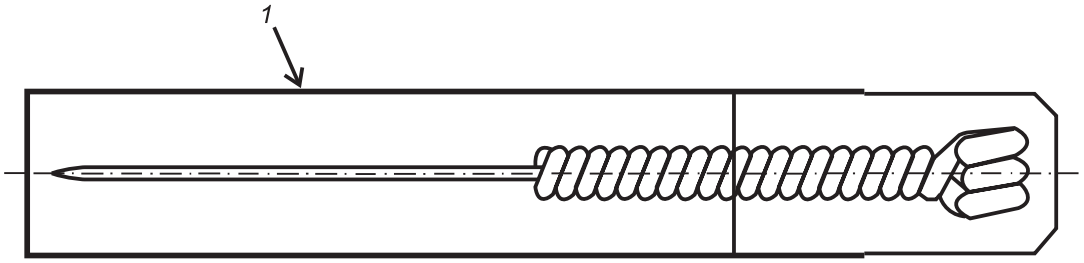
4.2 Acupuncture needle types

The acupuncture needle includes two types:

— acupuncture needle with a guide tube; and

— acupuncture needle without a guide tube.

The acupuncture needle with guide tube is shown in Figure 2. However, no uniform requirement is provided for the fixing method of the needle tube.



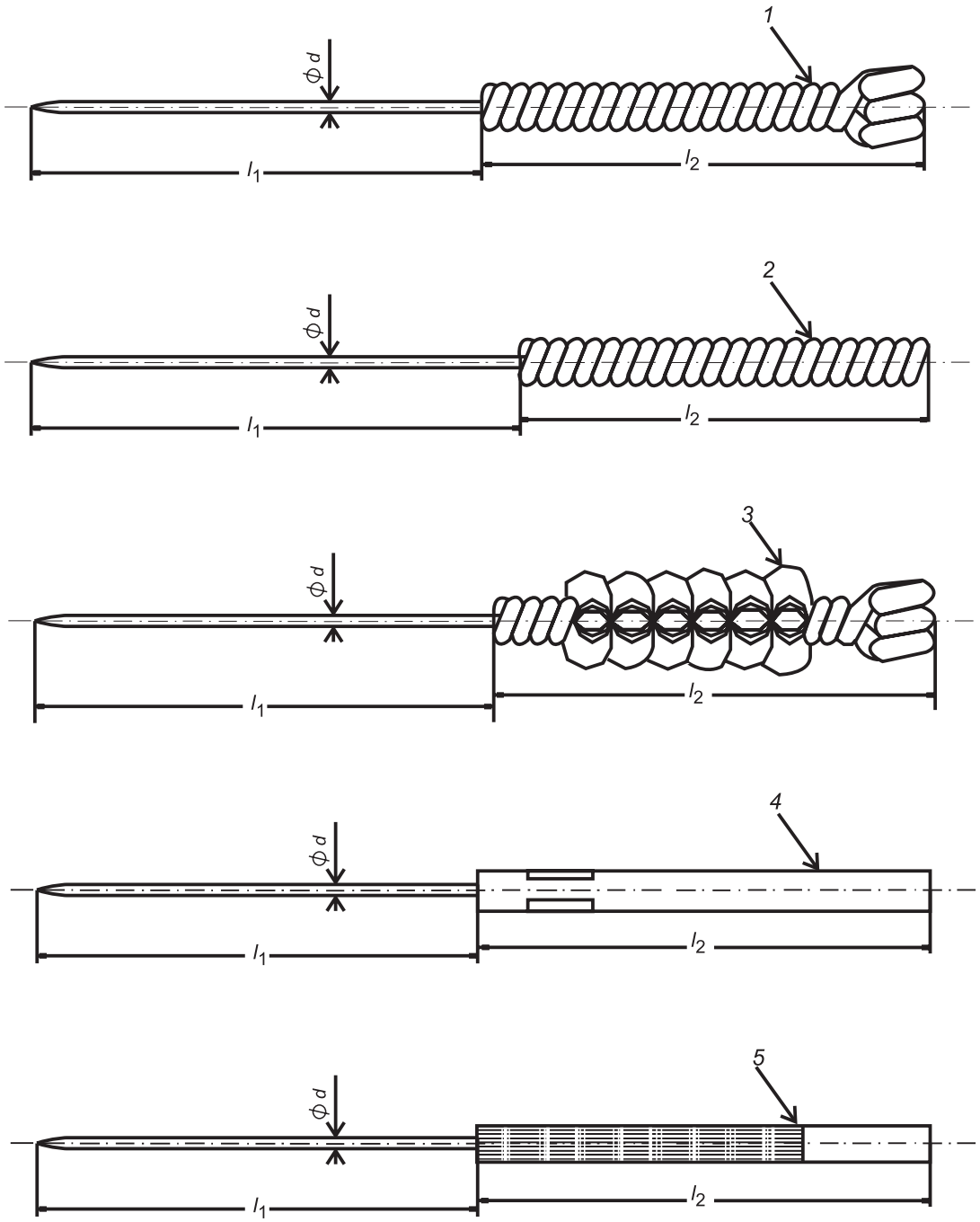
Key

1 guide tube

Figure 2 — The acupuncture needle with a guide tube

4.3 Types of needle handles

The types of needle handles include the ring handle, the plain handle, the flower handle, the metal tube handle, and the plastic handle, etc. The types of needle handles are not limited to those shown in the Figure 3.



Key

1 ring handle
2 plain handle
3 flower handle
4 metal tube handle
5 plastic handle

l_1 length of the needle body
l_2 length of the needle handle
⌀d diameter of the needle body

Figure 3 — Example of types of handles of acupuncture needles

5 Requirements

5.1 Materials

The biocompatibility of the body of the needle shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Compliance is demonstrated by:

a) analogy with published data; or

b) the selection of materials already shown to be biocompatible by proven clinical use in a similar application; or

c) experience with similar devices already on the market together with evidence of traceability to the materials used in the acupuncture needle; or

d) compliance with published procedures for biological evaluation of:

   1) Cytotoxicity;

   2) Sensitization;

   3) Intracutaneous reactivity;

   4) Ethylene oxide sterilization residuals (if using EO. to sterilize).

If the material of the body of the needle is changed and/or if there is a new coating on the surface of the needle body, and if there is risk indicating that these may cause side-effects to the human body, then testing should be in accordance with ISO 10993 series.

NOTE There is no uniform regulation regarding materials of the needle handle and body. Currently, the popularly used material of the needle body is made of X5CrNil8–9, X7CrNil8–9 Austenite Stainless Steel, etc. which are given in ISO 15510:2010.

5.2 Dimensions

5.2.1 Size designation

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

a) the nominal diameter of the body of acupuncture needle, expressed in millimetres; and

b) the nominal length of the body of acupuncture needle, expressed in millimetres.

The size of acupuncture needle shall be referred to as “the designated metric size” and specified as the diameter of the needle body × the length of the needle body.

EXAMPLE Ø 0,30 × 40 mm

5.2.2 Tolerance of dimensions

5.2.2.1 Diameter of the needle body

When measured by a micrometer or similar equipment, the nominal diameter of the body of acupuncture needle shall comply with Table 1.

Table 1 — Nominal diameter of needle body

Dimensions in millimetres

Nominal diameter of needle body d	Tolerance
$0{,}10 \leq d < 0{,}25$	±0,008
$0{,}25 \leq d \leq 0{,}45$	±0,015
$0{,}45 < d \leq 0{,}80$	±0,020

5.2.2.2 Length of body of the needle

When measured by vernier calipers or similar equipment, the nominal length of the body of acupuncture needle shall comply with Table 2.

Table 2 — Nominal length of needle body

Dimensions in millimetres

Nominal length of needle body l_1	Tolerance
$5 \leq l_1 \leq 25$	±0,50
$25 < l_1 \leq 60$	±1,00
$60 < l_1 \leq 100$	±2,00
$100 < l_1 \leq 200$	±3,00

5.2.3 Dimensions of needle handle

The handle of acupuncture needles shall be of suitable diameter and length for the intended purpose or manipulation.

The length of the handle of acupuncture needles (l_2) shall be no less than 13 mm.

The dimensions of the coiling handle wire used in the manufacturing of ring handles, plain handles and flower handles should comply with Table 3. The diameter of the plastic handle and the metal tube handle should comply with Table 4.

Table 3 — Diameter of the coiling handle wire

Dimensions in millimetres

Nominal diameter of needle body d	Diameter of the coiling handle wire
$0{,}10 \leq d < 0{,}20$	0,30
$0{,}20 \leq d < 0{,}30$	0,35
$0{,}30 \leq d < 0{,}40$	0,40
$0{,}40 \leq d < 0{,}50$	0,45
$0{,}50 \leq d \leq 0{,}80$	0,50

Table 4 — Diameter of the plastic handle and the metal tube handle and coiling handle which are joined by other method than coiling around the needle body

Dimensions in millimetres

Type of needle handle	Diameter of needle handle
Metal tube handle, Plastic handle, etc.	0,80 – 2,50
NOTE These diameters are only applicable to “Cylinder-shaped” handle.	

5.3 Performance requirements

5.3.1 Appearance and cleanliness

5.3.1.1 When inspected by normal or corrected-to-normal vision:

a) the surface of the acupuncture needles shall appear free from particles and extraneous matter;

b) the body of the needle shall be straight and there shall be neither breakage nor unevenness; and

c) the handle of needle shall not have any protuberances that could cause a scratch or cut, etc. If the handle of the needle is made of winding coils, the spiral loop should be arranged symmetrically without obvious gaps and the colour and lustre of the surface of the needle handle should be even. If the handle is plated, it shall not exhibit layering or shedding.

5.3.1.2 When examined under x 10 magnification:

a) the body of the needle shall be straight and there shall be neither breakage nor unevenness;

b) the body of the needle shall be smooth and clean:

   1) shall appear free from particles or extraneous matter produced during the metal processing course;

   2) shall not have any obvious defects such as ruggedness, scars, bends, grooves, rust or twist.

c) the tip of needle shall be sharp-edged, polished sharply and has no deficiencies of scars, fringes, spikes or hooks.

If the body of the acupuncture needle is lubricated, the lubricant shall not be visible under normal or corrected-to-normal vision as droplets of fluid on the surface of the needle body.

5.3.2 Drawing strength

The body of the needle shall be solidly joined to the handle of the needle at the root of the needle.

When the minimum static force given in Table 5 is applied in the direction of the centre axis of the body of the needle depending on the nominal diameter of the body of the needle, it shall not be drawn out of the handle of the needle. Axial displacement of the handle of the needle from the body of the needle of more than 3 mm is not permitted.

Table 5 — Force to test drawing strength

Nominal diameter of needle body *d* mm	Force N
0,10	5
0,10 < *d* ≤ 0,16	5,5
0,16 < *d* ≤ 0,20	7
0,20 < *d* ≤ 0,25	8
0,25 < *d* ≤ 0,35	15
0,35 < *d* ≤ 0,45	20
0,45 < *d* ≤ 0,55	25
0,55 < *d* ≤ 0,80	30

5.3.3 Hardness of the needle body

To assess the hardness test according to the requirements given in ISO 6507-1:2005 or other equivalent methods, the hardness of the body of the needle shall comply with Table 6.

Table 6 — Hardness of the needle body

Nominal diameter of needle body *d* mm	Hardness $HV_{0.2kg}$
0,10 ≤ *d* < 0,25	≥ 480, ≤ 680
0,25 ≤ *d* < 0,30	≥ 460, ≤ 655
0,30 ≤ *d* < 0,45	≥ 450, ≤ 655
0,45 ≤ *d* ≤ 0,80	≥ 420, ≤ 630
The hardness can also be converted into tensile strength. NOTE This hardness is only applicable to the stainless steel body of the needle.	

5.3.4 Resistance to breakage of the needle body

The body of the needle shall be of sufficient resistance to breakage.

After a body of the needle is coiled tightly around a mandrel which diameter is 3 times larger than the needle body, the body of the needle shall be free from any crack, break or separation of layers. In case of a body of the needle no more than 15 mm in length, the needle body shall be tested by being coiled twice circles around the mandrel tightly and a body of the needle longer than 15 mm shall be coiled five circles.

5.3.5 Intensity and puncture performance of the needle tip

5.3.5.1 General

The tip of the needle shall have good intensity and puncture performance.

5.3.5.2 Intensity and sharpness of the needle tip

When tested in accordance with Annex A, the tip of the needle shall have good intensity. The needle tips shall not have any hooks or bends after a set amount of pressure has been applied. The puncture force shall not exceed the values set forth in Table 7. The other equivalent method is available.

Table 7 — Pressure and puncture force

Nominal diameter of needle body d mm	Pressure N	Puncture force N
$0{,}10 \leq d \leq 0{,}12$	0,2	0,5
$0{,}12 < d \leq 0{,}25$	0,4	0,7
$0{,}25 < d \leq 0{,}35$	0,5	0,8
$0{,}35 < d \leq 0{,}45$	0,6	0,9
$0{,}45 < d \leq 0{,}80$	0,7	1,0

5.3.5.3 Puncture performance of the needle tip

When tested in accordance with Annex B, the tip of the needle should have good puncture performance. If the puncture force is low, this indicates that the needle tip is sharp. This can be selected for the performance of each manufacturer's needle tip.

5.3.6 Resistance to corrosion of the needle body

The body of the needle shall have good resistance to corrosion. If the conditions of storage have been met, there shall be no corrosion of the body of the needle before the expiry date.

When tested in accordance with Annex C, the partially immersed body of the needle shall show no evidence of corrosion resulting from the test. Annex C shall be applied only to the stainless steel body of the needle.

5.4 Sterility assurance

Sterile acupuncture needles for single use shall be sterilized through a validated sterilization process in order to ensure that the products are sterile.

NOTE For appropriate sterilization methods, see Bibliography. The requirements for validation and routine control of a sterilization process for medical devices are provided in ISO 11135-1, ISO 11137-1 and ISO 17665-1.

6 Package

6.1 Primary package

Sterile acupuncture needle shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

The material and design of this primary package shall not have detrimental effects on the contents. The material and design of this primary package should 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 package;

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

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

NOTE The requirements of materials, sterile barrier systems and packaging systems for terminally sterilized medical devices are provided by ISO 11607-1.

6.2 Secondary package

One or more primary packages shall be packaged in a secondary package.

The secondary package shall be sufficiently robust to protect the contents during handling, transit and storage.

One or more secondary packages may be packaged in a storage or a transit package.

7 Labelling

7.1 General

The symbols to be used with medical device labels, labelling, and information to be supplied on the package shall comply with ISO 15223-1.

7.2 Primary package

The primary package shall be marked with at least the following information:

a) the name or trade-mark or logo of the manufacturer and/or supplier;

b) a description of the contents, including the designated metric size in accordance with 5.2;

c) the lot number, prefixed by the word “LOT”, and/or date of manufacture;

d) expiry date;

e) method of sterilization, the word “STERILE” or symbol;

f) the words “For single use” or “Do not reuse” or symbol.

7.3 Secondary package

The secondary package shall be marked with at least the following information:

a) the name, address and trademark of the manufacturer and/or supplier;

b) description of the contents, including the designated metric size in accordance with 5.2, the quantity and the type;

c) the lot number, prefixed by the word “LOT”, and/or date of manufacture;

d) expiry date;

e) method of sterilization, the word “STERILE” or symbol;

f) the words “For single use” or “Do not reuse” or symbol;

g) if appropriate, the licensed certificate number according to the requirements of the regulations;

h) information for handling, storage and transportation;

i) a warning to check the integrity of each primary package before use, such as “Do not use if package is damaged” or symbol;

j) a warning that excessive electrical stimulation may cause corrosion to needles;

k) if used, the names or composition of additives (such as lubricant) used as a coating on the surface of needle body;

l) if appropriate, indication that the needles are not for use in moxibustion if the handle of the needle cannot tolerate the heat from the burning of moxa; and

m) if appropriate, those who are allergic to the material of the needle body should use with caution or follow the instruction of an acupuncture physician.

8 Transit and storage

8.1 The transport requirements should comply with the order contract.

8.2 The acupuncture needles should have sufficient protection from damage. Once the acupuncture needles are packaged, they should be stored in a clean, well-ventilated and non-contaminated environment. The storage environment should have controls in place for humidity, temperature and exposure to direct sunlight.

Annex A
(informative)

Test methods for the intensity and sharpness of the tip of the needle

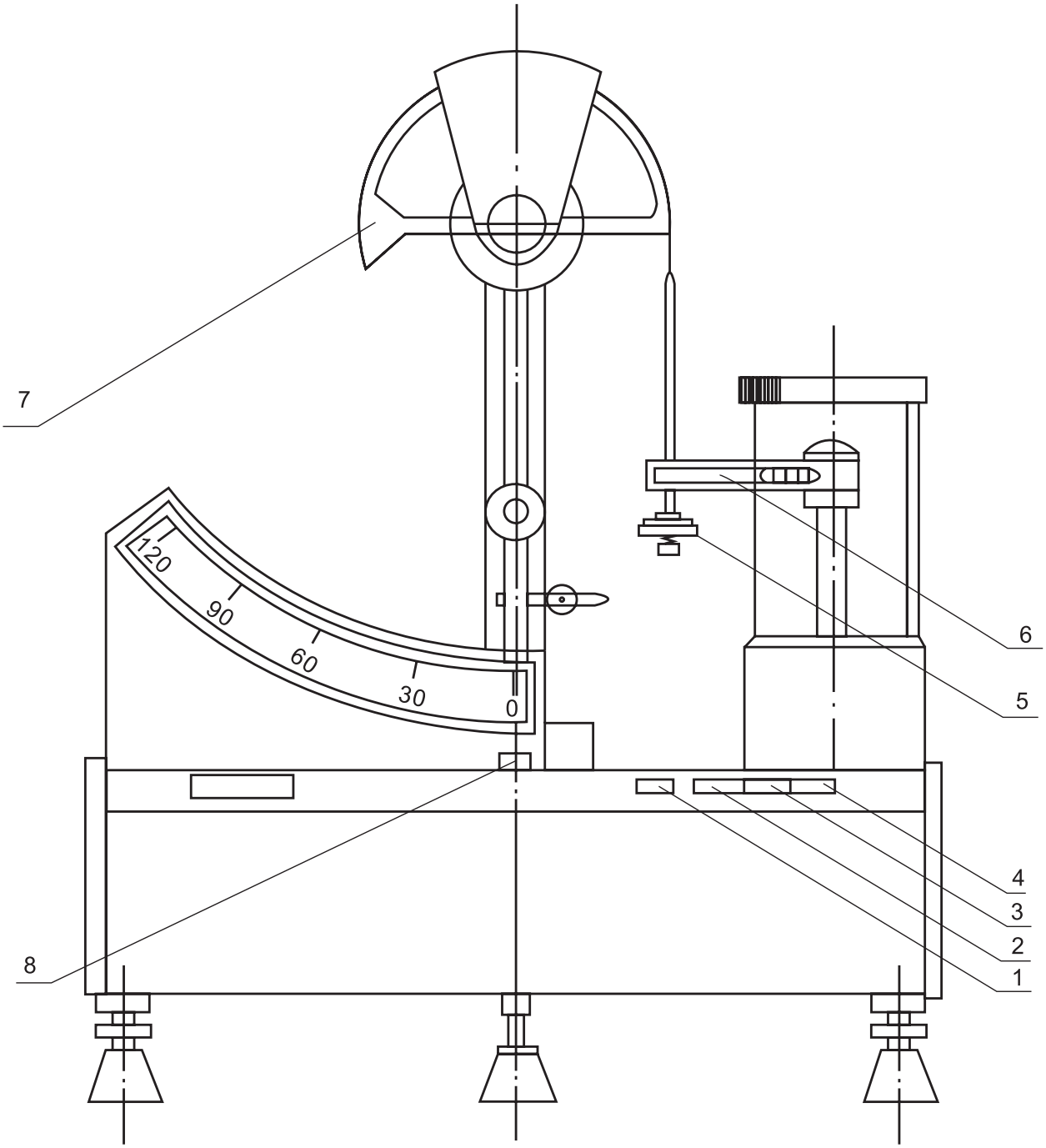
A.1 General

The intensity of the tip of the needle: refers to the needle tip ability to resist breakage when thrust vertically on the steel block.

The sharpness of the tip of the needle: refers to the force required by the needle tip to vertically pierce aluminium foil.

A.2 Apparatus for measuring

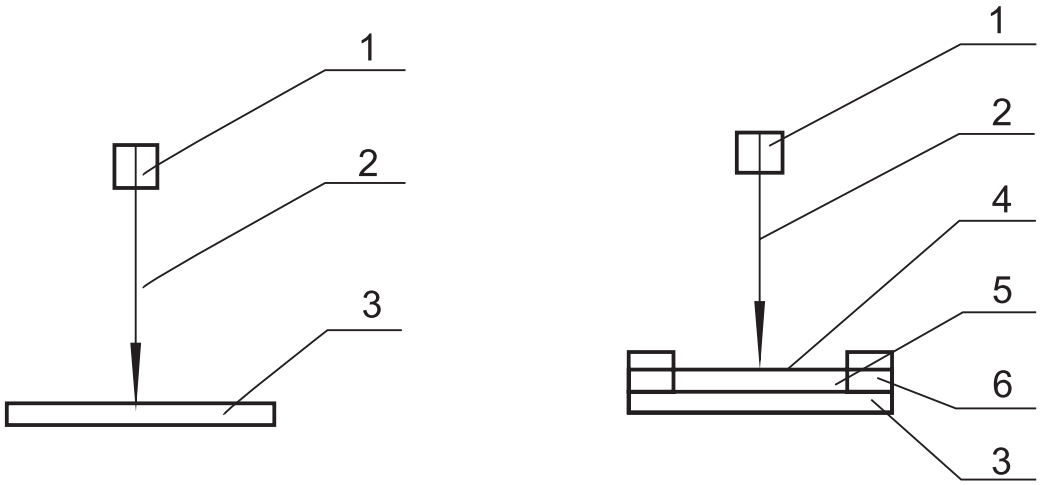
A.2.1 The typical apparatus for measuring the intensity and sharpness of the tip of the needle as shown in Figure A.1 and Figure A.2, they can also use the other equipment with the same performance, precision (including measuring amplifier installed on the equipment, data processing and display units, printers and floppy disks and other devices).



Key

1	power button (on and off)	5	aluminium foil clamping apparatus
2	function control button (on and off)	6	needle clamping apparatus
3	function control button (on and off)	7	adjustment rod
4	function control button (on and off)	8	(carpenter's) level

Figure A.1 — Example of typical apparatus for measuring



Intensity test **Sharpness test**

Key

1 clamped head
2 needle body
3 steel block
4 punctured material
5 gap
6 plate

Figure A.2 — Principles of testing for the intensity and sharpness of the needle tip

A.2.2 The full load, minimum value, and speed of the apparatus should comply with Table A.1.

Table A.1 — Hardness of the body of needle

Items	Designation
Full load	≤ 1,2 N
Minimum value	0,01 N
Speed	≤ 0,1 mm/s

A.2.3 The apparatus's erroneous differences in value shall be no more than 0,01 N.

A.2.4 The apparatus should have an auto-correction capability and an antishock device. The needle clamp should be stable during use.

A.2.5 The transmission of the apparatus should be sensitive and reliable.

A.2.6 The starting inductive quantity of the apparatus should be no more than 0,02 N.

A.2.7 The aperture of aluminium foil clamping apparatus is 5 mm, after clamping the Aluminium foil shall not loosen, and should be flat.

A.2.8 The steel block surface of the strength of the sample acupuncture needle tip should be smooth and without rust.

A.3 Aluminium foil

A.3.1 The aluminium foil surface should be clean and smooth and without overlaps, severe wrinkles, mildew stains, or sand holes.

A.3.2 The aluminium foil is a pliable material. The thickness should be (0,05 ± 0,002) mm and purity of no less than 99,5 %.

A.3.3 The strength of the pull resistance of the aluminium foil should be no less than 3 kg/mm^2, and the elongation should be no less than 3 %.

A.4 Procedure

A.4.1 Testing for the intensity of the needle tip: After the test sample is affixed to the apparatus (with 5 mm of the tip of the needle exposed), the needle tip is thrust vertically onto the steel block. According to A.2.2, increase force, speed and load until they reach the numerical values of the standard set by 5.3.5.2, removing the load after (5 to 10) s. Then, when examining the sample under x 5 magnification, the needle tip shall not have any bends or hooks. In addition, when the tip of the needle is dragged along the surface of cotton, it should not pull any fibres.

A.4.2 After the intensity test, keep the sample acupuncture needle clamped in the test apparatus and allow the needle to gradually increase its force exerted on the aluminium foil (by way of the transmission); the swaying rod will react accordingly. When the force acting on the acupuncture needle exceeds the resistance of the aluminium foil, the needle tip will pierce through the aluminium foil and come into contact with the electrode. The apparatus will automatically stop increasing the force. At this time, the value indicated by the pointer on the swaying rod is the piercing force of the needle tip. For other equipment, perform equivalent procedures in accordance with the apparatus being used.

A.4.3 Press the on-off button of the function controls to allow the swaying rod and pointer to return to their original positions. For other equipment, perform equivalent procedures in accordance with the apparatus being used.

A.4.4 Move the aluminium foil in the clamp to allow the distance between each pierced hole to exceed three times that of the test sample.

A.5 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the body of the needle;

b) the measured values of puncture force, expressed in newtons to the nearest 0,01 N;

c) the date of testing.

Annex B
(informative)

Test methods for the puncture performance of the tip of the needle

B.1 General

The test method in this annex is exemplary. Test conditions, test materials, and value limits should be determined by criteria and reference values depending on the size and characteristics of the needle.

Therefore, concerning the setting conditions, ranges, and precision of the testing apparatus, methods suiting the testing needles should be selected.

B.2 Method A — Qualitative test method

Cover the mouth of a cup (diameter of 100 mm) with the membrane of a surgical rubber glove (in accordance with ISO 10282) and tighten it properly with a rubber band. Puncture the membrane perpendicularly with the acupuncture needle. During the piercing, if the dent of the membrane is small and there is little resistance, this indicates that the needle tip is sharp. Otherwise, the needle tip is blunt.

NOTE This method can be qualitatively evaluated depending on the needle's puncture performance. This method is suitable for the cross-comparison of the purchaser and the quality control of production.

B.3 Method B — Quantitative test method

B.3.1 The testing apparatus for evaluating puncture performance

The apparatus should provide the following:

a) speed v = (50-250) mm/min; the average drive precision ≤ established drive speed ± 5 %;

b) average precision of the (0-50) sensor is ± 5 % of full range;

c) puncture diameter of polymerized film after clamping is 10 mm.

NOTE A sketch map produced by the typical apparatus for measuring and recording puncture force as shown in Figure B.1. Other apparatuses of similar performance and precision can also be used.

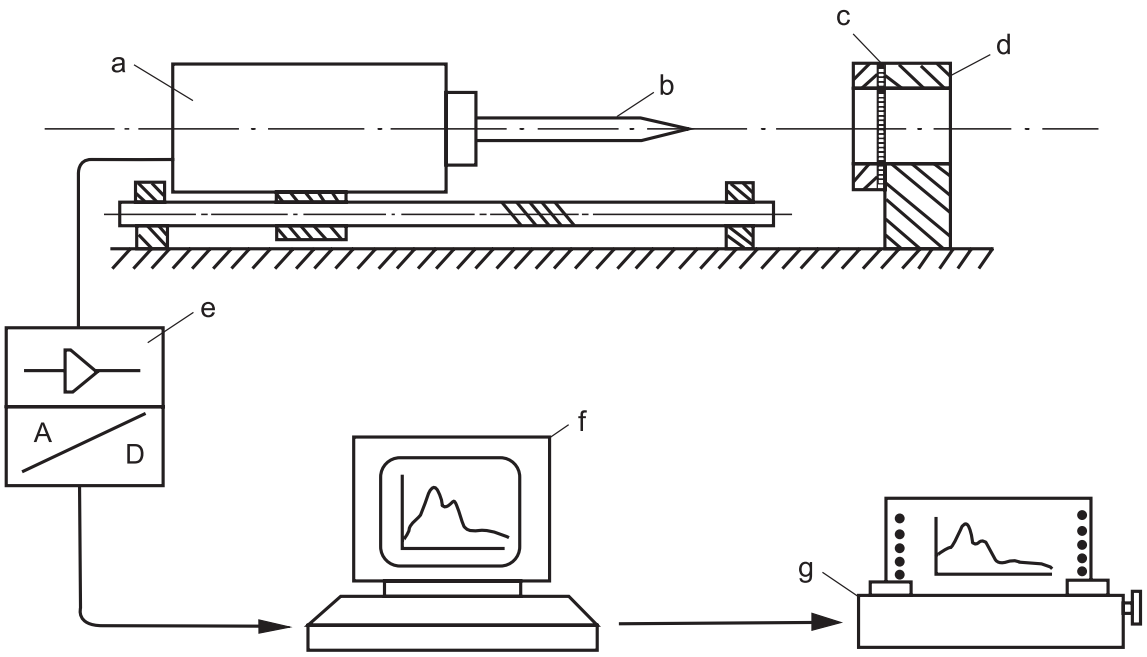


Figure B.1 — Sketch map produced by the typical testing apparatus

B.3.2 The polymerized film materials

The polymerized wax suitable for the piercing test is elastic with a thickness of (0,35 ± 0,05) mm. The Shore Hardness of the polyurethane film is (85 ± 10) Shore A.

B.3.3 Procedure

B.3.3.1 The polymerized film is placed in (22 ± 2)°C for 24 h and tested in the same temperature.

B.3.3.2 One part of the polymerized film of sequent length is clamped vertically on the apparatus. The polymerized film should not be tense. If the polymerized film has a refined processing surface, this surface should face the tip of the needle.

B.3.3.3 The handle of the needle of the test acupuncture needle is installed on the fixed apparatus and the body of the needle is placed perpendicularly to the surface of the polymerized film. The tip of the needle punctures the centre of the area.

B.3.3.4 The movement speed is 100 mm/min.

B.3.3.5 Turn on the testing apparatus.

B.3.3.6 Pierce the polymerized film and record the graph of force versus corresponding displacement.

B.3.3.7 Measure the corresponding peak values (f_0, f_1, and f_2).

B.3.3.8 Unused and non-punctured areas should be selected during every piercing of the polymerized film.

B.3.4 Recording the peak values of the coordinate figures

The various force values can be identified by observing the typical peak values during the puncturing of the polymerized film by the needle.

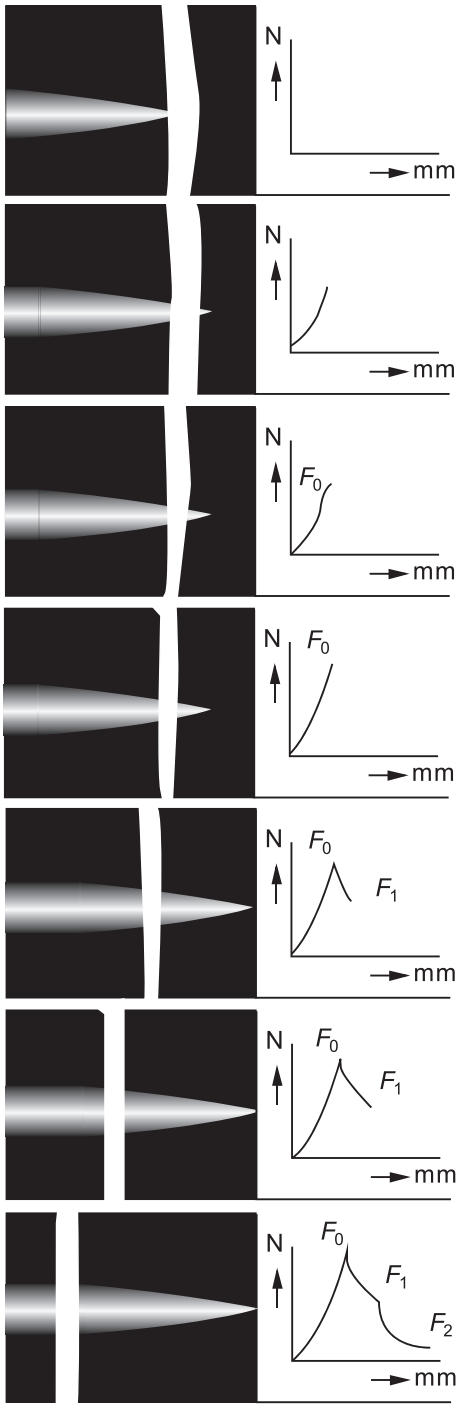
Diagram of the typical features of the needle piercing through the film are shown in Figure B.2.

Diagram of the typical puncture force of the needle (F_0, F_1, F_2) is shown in Figure B.3.

B.3.5 The results indicate

Compare with the same types of needles (of known quality and performance) to evaluate the coordinate graph of differences in force and position.

Puncture performance can be viewed as the peak values of force.



1 Initialization of needle movement

2 Needle comes into contact with film; force value increased and reaches F_0

3 Needle tip piercing through the film

4 The slant of the needle tip causes the film to expand; the force value falling to F_1

5 Part of the slant of the needle tip piercing through the film

6 Entire slant of the needle tip piercing through the film

7 Frictional movement of the needle tip; the force value falling to F_2

Key

F_0 the peak force of the needle tip piercing through the polymerized film

F_1 the peak force of the slanted surface of the needle tip cutting through the polymerized film

F_2 the frictional peak force of the length of the needle body piercing through the polymerized film

Figure B.2 — Diagram of the typical features of the needle piercing through the film

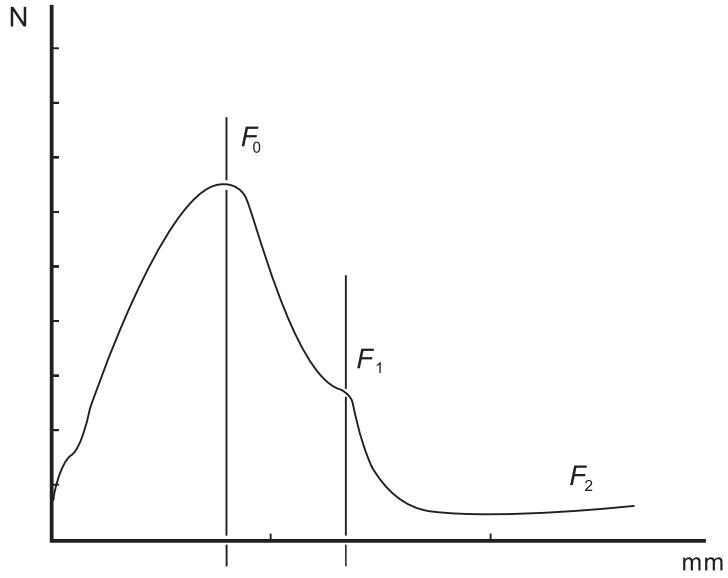


Figure B.3 — Diagram of the typical puncture force of the needle (F_0, F_1, F_2)

Annex C
(informative)

Test method for resistance to corrosion

C.1 Principle

The body of the needle is partially immersed in sodium chloride solution or citric acid solution for a specified time and afterwards the immersed portion is compared visually with the non-immersed portion for signs of corrosion.

C.2 Method A — Testing with sodium chloride solution

C.2.1 Reagents and apparatus

C.2.1.1 Reagents

c(NaCl) = 0,5mol/l (analytical grade reagent) in distilled or deionized water of grade 3 in accordance with ISO 3696.

C.2.1.2 Apparatus

Selection of laboratory borosilicate glassware.

C.2.2 Procedure

Any grease or dirt should be wiped off the Austenitic stainless steel of the body of the needle or manufactured needle body. After wiping, the test samples can be soaked in acetone or other organic solutions for further degreasing. The samples should then be washed and rinsed with the grade 3 water and set aside in preparation for later use.

Place a piece of body of the needle in a glass vessel (C.2.1.2) containing sodium chloride solution (C.2.1.1) at (23 ± 2) °C, so that approximately half the length of the body of the needle is immersed. Maintain the liquid and body of the needle at (23 ± 2)°C, for 7 h ± 5 min.

Remove the body of the needle, wipe it dry and compare the immersed and non-immersed portions under normal or corrected vision for signs of corrosion caused by the immersion. The partially immersed of the body of the needle shall show no evidence of corrosion resulting.

C.3 Method B — Testing with citric acid solution

C.3.1 Reagents and apparatus

C.3.1.1 Reagents

100 g/l (10 %) citric acid (chemically grade reagent) in distilled or deionized water of grade 3 in accordance with ISO 3696.

C.3.1.2 Apparatus

Selection of laboratory borosilicate glassware.

C.3.2 Procedure

Any grease or dirt should be wiped off the Austenitic stainless steel of the body of the needle or manufactured needle body. After wiping, the test samples can be soaked in acetone or other organic solutions for further degreasing. The samples should then be washed and rinsed with the grade 3 water and set aside in preparation for later use.

Soak the test samples in the citric acid solution and keep them in a room-temperature environment for 5 h ± 5 min. Remove the articles from the solution and wash them with the water of grade 3. Place the test samples in a glass vessel with the water of grade 3 and boil for (30 ± 5) min, to cool and keep them in a room-temperature setting for (48 ± 1) h.

Remove the test samples, wipe dry and compare the immersed and non-immersed portions of the body of the needle by normal or corrected-to-normal vision under x 10 magnification. The partially immersed of the body of the needle shall show no evidence of corrosion resulting.

C.4 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the body of the needle;

b) whether corrosion occurred on the immersed half during the test;

c) the date of testing.

Bibliography

[1] ISO 780:1997, *Packaging — Pictorial marking for handling of goods*

[2] ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

[3] ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

[4] ISO 6507-2:2005, *Metallic materials — Vickers hardness test — Part 2: Verification and calibration of testing machines*

[5] ISO 6507-3:2005, *Metallic materials — Vickers hardness test — Part 3: Calibration of reference blocks*

[6] ISO 6507-4:2005, *Metallic materials — Vickers hardness test — Part 4: Tables of hardness values*

[7] ISO 7864:1993, *Sterile hypodermic needles for single use*

[8] ISO 7000:2012, *Graphical symbols for use on equipment — Registered symbols*

[9] ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices (Amendment 1 published 2001)*

[10] ISO 10282:2002, *Single-use sterile rubber surgical gloves — Specification*

[11] ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[12] ISO 10993-5:2009, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

[13] ISO 10993-7:2008, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

[14] ISO 10993-10:2010, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

[15] ISO 10993-11:2006, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

[16] ISO 11135-1:2007, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

[17] ISO 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

[18] ISO 11137-2:2013, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

[19] ISO 11138-1:2006, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

[20] ISO 11138-2:2006, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

[21] ISO 11607-1:2006, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

[22] ISO 11607-2:2006, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

[23] ISO 11737-1:2006, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

[24] ISO 11737-2-2007, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the validation of a sterilization process*

[25] ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[26] ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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

[28] ISO 15223-2:2010, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

[29] ISO 15510:2010, *Stainless steels — Chemical composition*

[30] ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

[31] EN 980:2008, *Graphical symbols for use in the labelling of medical devices*

[32] EN 1041:2008, *Information supplied by the manufacturer with medical devices*

[33] EN 10088-1:2005, *Stainless steels*

[34] WFAS STANDARD – 001:2012, *Acupuncture needles*

[35] GB/T 1031-1995, *Surface roughness parameters and their values*

[36] GB 2024-1994, *Acupuncture needles*

[37] GB/DRT 2024-2010, *Acupuncture needles (Draft standard)*

[38] JIS T 9301:2005, *Acupuncture needle for single use*

[39] KS P 3007:2009, *Sterile disposable acupuncture needle*

[40] YY 0043-2005, *Medical suture needle*

[41] YY/T 0149-2006, *Medical instruments of stainless steel - Test methods of corrosive resistance*

[42] YY 0666-2008, *Method for the test of sharpness and strength of needles tips*

[43] 93/42/EEC, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

[44] 2007/47/EC, Directive of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

ICS 11.040.25
Price based on 24 pages