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Second edition
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Dentistry — Endodontic absorbent points

Médecine bucco-dentaire — Cônes absorbants utilisés en endodontie

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 1, *Filling and restorative materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7551:1996), which has been technically revised.

The main changes are as follows:

— the format has been updated;

— absorbent points other than standard taper absorbent points have been added;

— Table 2 has been added for the dimensions of greater taper absorbent points;

— the sizes of the absorbent points specified in this document have been aligned with the sizes for obturating points specified in ISO 6877 and for instruments from the ISO 6360 series;

— the nomenclature of “numbering system” has been changed to “nominal size designation” of the tip;

— Figure 2 has been removed.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The following information should be taken into account when using this document: specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document but it is recommended that, for the assessment of such biological risks, reference be made to ISO 7405 and ISO 10993-1.

Dentistry — Endodontic absorbent points

1 Scope

This document specifies the requirements and test methods for sterilized absorbent points used in endodontic procedures. Absorbent points are marketed sterilized or non-sterilized. The requirements apply to absorbent points which have been sterilized once in a manner approved by the manufacturer. This document specifies numerical systems and a colour-coding system for designating the sizes of absorbent points.

Clause 7 specifies the labelling and packaging needed, including the instructions for use. A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer (see Table 2). This document does not specify requirements or test methods for sterility.

NOTE 1 Reference to applicable national regulations can be made.

Reference is made to internationally accepted pharmacopoeia.

NOTE 2 National requirements can apply.

Standards on methods of validating sterilization processes are also available: ISO 11137-1, ISO 11137-2 and ISO 11137-3.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1, *Dentistry — Endodontic instruments — Part 1: General requirements*

ISO 6360-1, *Dentistry — Number coding system for rotary instruments — Part 1: General characteristics*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
absorbent point
elongated preformed cone or cylinder of a material suitable for absorption of liquids from a root canal, having a rounded, conical or blunt tip, and a neck that is tapered or cylindrical, or a combination of both

Note 1 to entry: The absorbent points may be used to apply a small quantity of a liquid disinfectant into the root canal for a short period.

3.2
nominal size designation
size of the tip, designated as *D*, measured in hundredths of a millimetre, indicated as "000"

3.3
taper
percentage increase in diameter along the length of the *absorbent point* (3.1) from the tip

EXAMPLE 02 taper represents a 2 % increase in diameter along the length of the absorbent point.

3.4
standard absorbent point
absorbent point (3.1) having a uniform 02 *taper* (3.3) over the first 16 mm from the tip

3.5
greater taper absorbent point
absorbent point (3.1) having a uniform *taper* (3.3) greater than 02 over the first 16 mm from the tip

3.6
variable taper absorbent point
absorbent point (3.1) having a *taper* (3.3) that varies over the first 16 mm from the tip

3.7
auxiliary absorbent point
absorbent point (3.1) excepting *standard absorbent point* (3.4), *greater taper absorbent point* (3.5) and *variable taper absorbent point* (3.6), not subject to *nominal size designation* (3.2) requirements

3.8
tip
distal end of an *absorbent point* (3.1) that is first inserted into a root canal

3.9
neck
portion of an *absorbent point* (3.1) for grasping while inserting the distal end in the root canal

3.10
unit pack
smallest pack of *absorbent points* (3.1) distributed, containing one or more sizes of absorbent points

4 Requirements

4.1 Appearance

An absorbent point shall be smooth and uniform in appearance throughout its length, free from extraneous matter and fibres projecting from the absorbent point. Test in accordance with 6.2.

4.2 Length

The overall length shall be not less than 28 mm, unless otherwise stated by the manufacturer. If some other length is stated, the absorbent point shall not be less than the stated length. Test in accordance with 6.3.

4.3 General

The designation for standard absorbent point, greater taper absorbent point, and variable taper absorbent point shall be in the form of a five-digit numerical set, having two parts: 000 XX, where 000 corresponds to the nominal size designation and XX corresponds to the two significant figures of the taper per cent. For example, a 2 % taper is designated as 02. The nominal size designation shall include the specified colour or its abbreviation.

4.4 Nominal size designation tolerances

The diameter tolerances of D, d_3 and d_{16} for standard absorbent points and greater taper absorbent points (see Figure 1) shall be:

— ±0,05 mm for absorbent point of sizes 008 to 060;

— ±0,07 mm for absorbent point of sizes 070 to 140.

For a variable taper absorbent point, two reference locations shall be used for the calculation of D within the first taper section of the absorbent point. The diameter tolerance shall be:

— ±0,05 mm for absorbent point of sizes 008 to 060;

— ±0,07 mm for absorbent point of sizes 070 to 140.

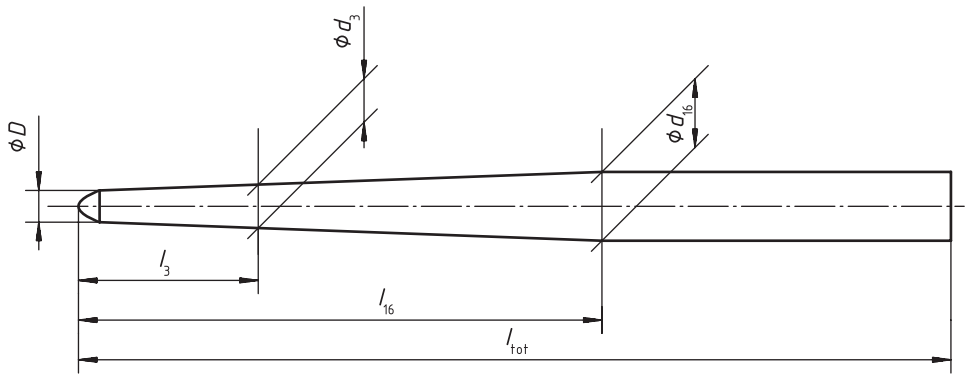
The diameter tolerance for an auxiliary absorbent point shall be ±0,05 mm for all auxiliary absorbent point sizes.

The dimensions of standard absorbent points and greater taper absorbent points shall comply with Table 1 and Figure 1. Within the dimensions specified, variations in shape and design are permitted. Testing for compliance shall be carried out in accordance with ISO 3630-1, and in accordance with 6.2 and 6.3. The dimensions of the absorbent points shall be as shown in Table 1.

For variable taper absorbent point, the manufacturer shall designate two reference locations to describe the taper section nearest the tip. The reference locations (length from the tip) shall be designated as l_x and l_y ($l_x < l_y$), and the corresponding diameters, d_x and d_y shall be measured. The diameter tolerance of a variable taper absorbent points at l_y, shall be ±0,05 mm.

The diameters at l_{16} or l_y (d_{16} or d_y) shall be verified to be within tolerance for absorbent points.

The tip of absorbent points shall be rounded, conical or blunt. The neck may be continuously tapered or cylindrical, or a combination of both.



Key

D	nominal size designation, mm	l_{tot}	overall length, mm
d_3	diameter, mm	l_3	length, mm
d_{16}	diameter, mm	l_{16}	length, mm

NOTE 1 Table 1 gives values of d_3 and d_{16} for each size of standard absorbent points only.

NOTE 2 The manufacturer is responsible for the exact shape of the tip.

Figure 1 — Diagrammatic representation of a standard or greater taper absorbent point

Table 1 — Nominal size designation, tip diameters and colour-coding for standard absorbent points

Dimensions in millimetres

Nominal size designation	D	d_3	d_{16}	Colour	Abbreviation
Tolerance ±0,05 mm					
008	0,08	0,14	0,40	grey	gry
010	0,10	0,16	0,42	purple	pur
015	0,15	0,21	0,47	white	wht
020	0,20	0,26	0,52	yellow	yel
025	0,25	0,31	0,57	red	red
030	0,30	0,36	0,62	blue	blu
035	0,35	0,41	0,67	green	grn
040	0,40	0,46	0,72	black	blk
045	0,45	0,51	0,77	white	wht
050	0,50	0,56	0,82	yellow	yel
055	0,55	0,61	0,87	red	red
060	0,60	0,66	0,92	blue	blu
Tolerance ±0,07 mm					
070	0,70	0,76	1,02	green	grn
080	0,80	0,86	1,12	black	blk
090	0,90	0,96	1,22	white	wht
100	1,00	1,06	1,32	yellow	yel
110	1,10	1,16	1,42	red	red
120	1,20	1,26	1,52	blue	blu
130	1,30	1,36	1,62	green	grn
140	1,40	1,46	1,72	black	blk

4.5 Colour-coding

The unit pack shall show that the colour corresponding to the nominal size designation, *D*, in Table 1 for a standard absorbent point, greater taper absorbent point and variable taper point absorbent point. Colour-coding is optional on the individual absorbent points; if used, the colours shall conform to Table 1. Colour-coding is optional for auxiliary absorbent points.

NOTE 1 Colour-coding of individual points can be confined to the neck.

NOTE 2 No colour-code system has been designated for taper.

4.6 Taper

The taper of the absorbent points shall be verified using measurements of the diameters at two distances from the tip of the point.

a) The taper of a standard absorbent point, greater taper absorbent point and an auxiliary absorbent point shall be uniform for a minimum of 16 mm from the tip (see Figure 1), increasing at the taper designated by the manufacturer along their length.

b) The tapers of the variable taper absorbent point shall be designated by the manufacturer. The length and taper of the section closest to the tip shall be stated by the manufacturer by providing the dimensions of l_x, l_y and the taper.

c) Test in accordance with 6.4, to calculate the taper and confirm the nominal size designation.

d) The nominal size designation of the tip, except for auxiliary absorbent points shall be in accordance with the numbering system shown in Table 1.

NOTE The tip size, shape and taper or shape of the auxiliary absorbent points is left to the discretion of the manufacturer.

4.7 Absorption

The absorbent point shall absorb liquid to a height of 10 mm or more above the liquid level when tested in accordance with 6.5.

4.8 Disintegration

The absorbent point shall not visually disintegrate or change shape while immersed in water at (37 ± 2) °C for (10 ± 1) min or during removal from the water with forceps. Test in accordance with 6.2.

5 Procurement of samples

Use one or more retail packages from the same batch, containing sufficient material to carry out the specified tests, plus an allowance for repeats, if necessary. Procure at least 20 absorbent points of any size or taper to be tested.

6 Measurement and test methods

6.1 Test conditions

Conduct all tests at (23 ± 2) °C and a relative humidity of (50 ± 20) %. Condition the absorbent points at this temperature and humidity for 1 h prior to testing.

If non-sterile, sterilize the absorbent points once, as recommended by the manufacturer, then precondition for at least 1 h in the test atmosphere.

6.2 Visual examination

The appearance, length and taper of the absorbent points shall be verified using visual examination and measurement.

a) Select 10 standard absorbent points, greater taper absorbent points or auxiliary absorbent points at random, of any size and taper.

b) Visually examine, without magnification, absorbent points for a smooth and uniform appearance, free from extraneous matter and fibres projecting from the absorbent point, as specified in 4.1.

The observer shall have normal visual acuity.

If all 10 absorbent points pass, the product passes. If eight or fewer absorbent points pass, the product fails. If nine absorbent points pass, test 10 additional absorbent points, randomly selected; all 10 additional absorbent points shall pass for the product to comply.

6.3 Length

6.3.1 Apparatus

Visual measurement apparatus shall be used for measuring the length with a minimum accuracy of 0,1 mm.

6.3.2 Method

The length of the point shall be verified by measurement from the tip to the end of the point.

a) Select 10 absorbent points at random of any size and taper.

b) Use the visual measuring equipment to measure and record the overall length l_{tot} (mm), as defined in Figure 1 for confirmation 4.2.

If all 10 absorbent points pass, the product passes. If eight or fewer absorbent points pass, the product fails. If nine absorbent points pass, test 10 additional absorbent points; all 10 shall pass for the product to comply.

6.4 Taper and nominal size measurements

6.4.1 Apparatus

Visual measuring equipment, such as an optical comparator, calibrated to an accuracy of 0,001 mm to measure an absorbent point.

6.4.2 Method for standard and greater taper points

The taper of the standard and greater taper absorbent points shall be verified using measurements of the diameters at 3 mm and 16 mm from the tip of the point.

a) Select 10 standard absorbent points, greater taper absorbent points or auxiliary absorbent points at random of any size and taper.

b) Use the visual measuring equipment to measure and record the diameters, d_3 and d_{16} (mm), at lengths l_3 and l_{16} (mm), defined in Figure 1.

c) Calculate the taper, T, for each point measured using Formula (1):

$$T_{calculated} = 100 \times (d_{16} - d_3) / 13 \quad (1)$$

d) Calculate D for each point using either Formula (2) or Formula (3).

$$D_{\text{calculated}} = d_{16} - 16 \times T_{\text{calculated}} \ / 100 \tag{2}$$

$$D_{\text{calculated}} = d_{16} - (d_{16} - d_3) \times 16 / 13 \tag{3}$$

e) Tabulate the data for each absorbent point.

f) For a standard absorbent point or a greater taper absorbent point, compare the values D, d_3 and d_{16} (mm) against those in Tables 1 and 2, considering the tolerances in 4.4. Table 1 has the dimensions for standard taper points. Table 2 has the dimensions for several tapers of absorbent point.

g) Determine whether each standard absorbent point complies with the requirements of Table 1, determine whether each greater taper absorbent point comply with the requirements of Table 2 for D, d_3 and d_{16}, including the tolerances in 4.4.

If the values pass for d_3, d_{16} and D for all 10 absorbent points, the product passes. If eight or fewer absorbent points pass, the product fails. If nine absorbent points pass, test 10 additional, randomly selected absorbent points; all 10 shall pass for the product to comply.

Table 2 — Sizes of points at D, d_3 and d_{16} for greater taper absorbent points

Size designation	Standard 2% taper	Taper %					
d_3	D (±0,05)	**3**	**4**	**5**	**6**	**7**	**8**
8	0,08	0,17	0,20	0,23	0,26	0,29	0,32
10	0,10	0,19	0,22	0,25	0,28	0,31	0,34
15	0,15	0,24	0,27	0,30	0,33	0,36	0,39
20	0,20	0,29	0,32	0,35	0,38	0,41	0,44
25	0,25	0,34	0,37	0,40	0,43	0,46	0,49
30	0,30	0,39	0,42	0,45	0,48	0,51	0,54
35	0,35	0,44	0,47	0,50	0,53	0,56	0,59
40	0,40	0,49	0,52	0,55	0,58	0,61	0,64
45	0,45	0,54	0,57	0,60	0,63	0,66	0,69
50	0,50	0,59	0,62	0,65	0,68	0,71	0,74
55	0,55	0,64	0,67	0,70	0,73	0,76	0,79
60	0,60	0,69	0,72	0,75	0,78	0,81	0,84
d_3	D (±0,07)	**3**	**4**	**5**	**6**	**7**	**8**
70	0,70	0,79	0,82	0,85	0,88	0,91	0,94
80	0,80	0,89	0,92	0,95	0,98	1,01	1,04
90	0,90	0,99	1,02	1,05	1,08	1,11	1,14
100	1,00	1,09	1,12	1,15	1,18	1,21	1,24
110	1,10	1,19	1,22	1,25	1,28	1,31	1,34
120	1,20	1,29	1,32	1,35	1,38	1,41	1,44
130	1,30	1,39	1,42	1,45	1,48	1,51	1,54
140	1,40	1,49	1,52	1,55	1,58	1,61	1,64
d_{16}	D (±0,05)	**3**	**4**	**5**	**6**	**7**	**8**
8	0,08	0,56	0,72	0,88	1,04	1,20	1,36
10	0,10	0,58	0,74	0,90	1,06	1,22	1,38
15	0,15	0,63	0,79	0,95	1,11	1,27	1,43
20	0,20	0,68	0,84	1,00	1,16	1,32	1,48
25	0,25	0,73	0,89	1,05	1,21	1,37	1,53

Table 2 *(continued)*

Size designation	Standard 2% taper	Taper %					
30	0,30	0,78	0,94	1,10	1,26	1,42	1,58
35	0,35	0,83	0,99	1,15	1,31	1,47	1,63
40	0,40	0,88	1,04	1,20	1,36	1,52	1,68
45	0,45	0,93	1,09	1,25	1,41	1,57	1,73
50	0,50	0,98	1,14	1,30	1,46	1,62	1,78
55	0,55	1,03	1,19	1,35	1,51	1,67	1,83
60	0,60	1,08	1,24	1,40	1,56	1,72	1,88
d_{16}	D (±0,07)	**3**	**4**	**5**	**6**	**7**	**8**
70	0,70	1,18	1,34	1,50	1,66	1,82	1,98
80	0,80	1,28	1,44	1,60	1,76	1,92	2,08
90	0,90	1,38	1,54	1,70	1,86	2,02	2,18
100	1,00	1,48	1,64	1,80	1,96	2,12	2,28
110	1,10	1,58	1,74	1,90	2,06	2,22	2,38
120	1,20	1,68	1,84	2,00	2,16	2,32	2,48
130	1,30	1,78	1,94	2,10	2,26	2,42	2,58
140	1,40	1,88	2,04	2,20	2,36	2,52	2,68

6.4.3 Method for variable taper absorbent points

The taper of the variable taper absorbent points shall be verified using measurements of the diameters at two distances from the tip of the point.

a) Select 10 variable taper absorbent points at random of any size.

b) Visually examine to measure and record the diameters d_x and d_y from the two reference locations, l_x and l_y, designated by the manufacturer. These locations are within the first taper section of the absorbent point near the tip.

NOTE l_y is farther from the tip than l_x.

c) Calculate the initial taper using Formula (4):

$$T_{\text{calculated}} = 100 \times (d_y - d_x)/(l_y - l_x) \quad (4)$$

d) Calculate D for each variable taper absorbent point using Formula (5):

$$D_{\text{calculated}} = d_x - (l_x \times T_{\text{calculated}}/100) \quad (5)$$

e) Tabulate the data for each variable taper absorbent point and record whether each point complies with the values provided by the manufacturer, including the tolerances in 4.4.

If the values for d_x, d_y and D for all 10 variable taper absorbent point pass, the product passes. If eight or fewer variable taper absorbent point points pass, the product fails. If nine variable taper absorbent point points pass, test 10 additional, randomly selected variable taper absorbent point points; all 10 shall pass for the product to comply.

6.5 Absorption

6.5.1 Apparatus

6.5.1.1 Glass beaker of sufficient depth to accommodate absorbent points.

6.5.1.2 Suspending apparatus.

6.5.1.3 Calibrated ruler or similar device with a precision of ±0,5 mm.

6.5.1.4 Forceps for grasping the neck of absorbent points.

6.5.2 Material

Acid yellow 23 dye (C.1.19140, tartrazine) (0,4 % concentration in water).

6.5.3 Method

The ability of the absorbent points to absorb water-based liquids shall be visually assessed using a water-based solution and measuring the dye absorption above the surface of the liquid.

a) Use the suspending apparatus to insert the absorbent points vertically in the Acid yellow 23 solutions.

b) Immerse the absorbent points to a depth of 5 mm using the suspending apparatus, keeping the points isolated from the container's sides and other test pieces.

c) After 60 s, quickly remove the absorbent point and record the total distance, to the nearest 0,5 mm, at which the dye is observed from the tip of the absorbent point as defined in Figure 1 for confirmation as given in 4.7. The total dyed distance shall exceed 15 mm from the tip.

6.5.4 Interpretation of results

If all 10 absorbent points pass the requirement, the product passes. If eight or fewer absorbent points pass, the product fails. If nine absorbent points pass, test 10 additional, randomly selected absorbent points; all 10 shall pass for the product to comply.

7 Product information

7.1 Marking

Packaging, marking, instructions and information is supplied by the manufacturer.

The nominal size designation or colour-code of an absorbent point shall be marked on the non-tip end. Markings shall comply with ISO 3630-1 and Table 1.

7.2 Packaging

Absorbent points shall be supplied in unit-pack containers that afford adequate protection and have no adverse effect on the quality of the contents. When sterility is claimed (see Table 3), the product shall maintain sterility until first opened.

7.3 Labelling

Information shall be clearly marked on the outermost packaging or containers (for multi-dose packs), as indicated in Table 3 and conform to ISO 20417.

Visually inspect to verify that the requirements in Table 3.

NOTE 1 Additional information to that specified in Table 3 can be supplied at the discretion of the manufacturer.

NOTE 2 Table 3 contains optional items and serves as a guide to the manufacturer as to the type of information which can be useful to dentists.

Table 3 — Requirements for labelling

	Information	Outermost packaging	Instructions for use or other labelling
1	The trade name of the product or a means of identification.	M	M
2	Labels shall display the name of the manufacturer.	M	M
3	The address of the manufacturer or its authorized representative responsible for the country of sale. Trademark or registered mark shall be included.	M	M
4	Graphical symbols shall be in accordance with ISO 15223-1, if applicable.	M	M
5	The manufacturer's internet address (URL), if one exists. However, where instructions for use are provided on a medium other than paper, the manufacturer should ensure the user has information on how to view the instructions for use, access the correct version of the instructions for use; and obtain a paper version of the instructions for use.	OPT	OPT
6	The recommended conditions of storage.	M	M
7	The lot identification and product identification, consisting of a serial number or a combination of letters and numbers and a unique device identifier (UDI) that refers to the manufacturer's records for that particular batch of material.	M	NA
8	If device is intended for single use.	OPT	M
9	The expiry date shall be expressed in accordance with ISO 8601-1 for the material if stored under the manufacturer's recommended conditions.	M	OPT
10	The presence of hazardous substances in respect of such properties as toxicity, hazard, flammability or tissue irritancy, for both patient and operator, indicated by text or symbol.	OPT	M
11	The identification of the material and the product, absorbent points. Size and taper designation (see 4.3), minimum number of absorbent points in the unit pack and nominal length of the absorbent points.	M	M
12	The nominal size designation and taper of the absorbent points, except auxiliary points. Variable taper absorbent points should include initial taper and length thereof.	M	M
13	When the package is sterile, it shall be marked with the symbol for "Sterile" in accordance with ISO 6360-1. If the manufacturer claims that the contents of the unopened pack are sterile, it shall be marked with the word "STERILE", in accordance with ISO 15223-1, and the expiry date in accordance with ISO 8601-1. For bulk packs of points marked "STERILE", a statement shall be added to the effect that sterility is not guaranteed after the pack is opened. A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer (see Table 2). This document does not specify requirements or test methods for sterility. NOTE 1 Reference to applicable national regulations can be made. Reference is made to internationally accepted pharmacopoeia. NOTE 2 National requirements exist can apply. Standards on methods of validating sterilization processes are also available: ISO 11137-1, ISO 11137-2 and ISO 11137-3.	M	M, if sterility is claimed, otherwise, NA
14	The net mass or number in each container.	M	OPT
15	The indications for clinical use. Where instructions for use are provided on a medium other than paper, the manufacturer should ensure the user has information on how to view the instructions for use, access the correct version of the instructions for use; and obtain a paper version of the instructions for use.	OPT	M
16	Instructions for use shall be provided with the following information:	NA	M

Key

M: mandatory

OPT: informative but optional

NA: not applicable