BRITISH STANDARD

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Non-active medical devices — Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

The European Standard EN 14079:2003 has the status of a British Standard

ICS 11.120.20

BSI
British Standards

National foreword

This British Standard is the official English language version of EN 14079:2003.

The UK participation in its preparation was entrusted by Technical Committee CH/205, Non-active medical devices, to Subcommittee CH/205/1, Medical textiles, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

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

Cross-references

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Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

Dispositifs médicaux non actifs - Exigences de performance et méthodes d'essais pour la gaze de coton absorbante et la gaze de coton et viscose absorbante

Nichtaktive Medizinprodukte - Leistungsanforderungen und Prüfverfarhen für Verbandmull aus Baumwolle und Verbandmull aus Baumwolle und Viskose

This European Standard was approved by CEN on 21 February 2003.

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 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 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

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Foreword

This document (EN 14079:2003) has been prepared by Technical Committee CEN /TC 205, "Non-active medical devices" the secretariat of which is held by BSI.

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 October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

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.

This standard is based on the European Pharmacopoeia monographs. As charged by CEN/TC 205 it is a mere reformatting of the monographs. It includes requirements and test methods as far as they are in line with the essential requirements as defined in Annex I of the Medical Device Directive 93/42/EEC. This standard does not describe the full state of the art and therefore will be revised immediately after finalization.

Annexes A and B are normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Absorbent cotton gauze, absorbent cotton ribbon gauze and absorbent cotton and viscose ribbon gauze were described in the European Pharmacopoeia. Due to the introduction of the Medical Device Directive 93/42/EEC, those monographs have been removed from the European Pharmacopoeia.

1 Scope

This standard describes the requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauzes. The standard does not consider gauzes impregnated with a pharmaceutical substance.

2 Normative references

This standard contains no normative references

3 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply:

3.1
absorbent cotton gauze
cotton cloth of plain weave, bleached to a good white and purified, being white and practically odourless, containing not more than slight traces of leaf, pericap seed-coat or other impurities and reasonably free from weaving defects

3.2
absorbent cotton ribbon gauze
woven cloth supplied in continuous ribbons of various widths with fast selvedges, made from cotton threads that are purified, bleached and made absorbent either before or after weaving, being white and practically odourless, containing not more than slight traces of leaf, pericap seed-coat or other impurities and reasonably free from weaving defects

3.3
absorbent cotton and viscose ribbon gauze
woven cloth supplied in continuous ribbons of various widths with fast selvedges, having in the warp cotton threads and in the weft viscose threads or combined cotton and viscose threads, made from threads that are purified, bleached and made absorbent either before or after weaving, being white and practically odourless, containing not more than slight traces of leaf, pericarp seed-coat or other impurities and reasonably free from weaving defects

4 Requirements

4.1 Fibre Identification

4.1.1 Absorbent cotton gauze and absorbent cotton ribbon gauze

When tested according to 5.2.1 the cotton fibres shall conform to the IDENT tests A, B and C.

4.1.2 Absorbent cotton and viscose ribbon gauze

When tested according to 5.2.2 the cotton fibres shall conform to the IDENT tests A and C and the viscose fibres shall conform to IDENT test B.

If it is necessary to differentiate between lustrous or matt viscose, the IDENT test D shall be used.

4.2 Acidity and alkalinity

When tested according to 5.3 neither solution shall be pink.

4.3 Foreign fibres

When tested according to 5.4 the cotton and viscose fibres shall conform to 5.4, only occasionally a few isolated foreign fibres being allowed.

4.4 Fluorescence

When tested according to 5.5 the cotton and viscose gauzes shall conform to 5.5.

4.5 Thread count

When tested according to 5.6 the thread counts per 100 mm shall be as given in Table 1 and Table 2.

Table 1 — Textile and physical requirements for absorbent cotton gauze

Type (number of threads per cm^2)	Threads in warp per 100 mm	Minimum breaking load in Newton per 50 mm warp way	Threads in weft per 100 mm	Minimum breaking load in Newton per 50 mm weft way	Minimum mass in g/m^2
12	73 ± 4	-	45 ± 4	-	13,0
13 light	73 ± 4	-	57 ± 4	-	14,0
13 heavy	70 ± 4	35	60 ± 4	20	17,0
17	100 ± 5	50	70 ± 4	30	23,0
18	100 ± 5	50	80 ± 5	30	24,0
20	120 ± 6	60	80 ± 5	35	27,0
22	120 ± 6	60	100 ± 5	40	30,0
24 a	120 ± 6	60	120 ± 6	50	32,0
24 b	140 ± 6	70	100 ± 6	40	32,0

Table 2 — Textile and physical requirements for absorbent cotton ribbon gauze and absorbent cotton and viscose ribbon gauze

Type (number of threads per cm^2)	Threads in warp per 100 mm	Minimum breaking load in Newton per 50 mm warp way	Threads in weft per 100 mm	Minimum mass in g/m^2
22 a	120 ± 3 [a]	60	100 ± 5	33,5
22 b	120 ± 3 [a]	60	100 ± 5	44,0
24 a	120 ± 3 [a]	60	120 ± 6	36,0
[a] The limits are increased to ± 4 for ribbon gauze 25 mm or 50 mm wide and to ± 8 for ribbon gauze 12,5 mm wide.				

4.6 Mass per square metre

When tested according to 5.7 the mass per square metre in grams shall be as given in Table 1 and Table 2.

4.7 Minimum breaking load

When tested according to 5.8 the minimum breaking load in Newton per 50 mm shall be as given in Table 1 and Table 2.

4.8 Sinking time

When tested according to 5.9 the sinking time shall not exceed 10 s.

4.9 Ether-soluble substances

When tested according to 5.10 the amount of ether-soluble substances shall not be more than 0,50 % .

4.10 Surface active substances

When tested according to 5.11 the froth height above the surface of the liquid after 300 s shall not exceed 2 mm.

4.11 Water-soluble substances

When tested according to 5.12 the amount of water-soluble substances shall not be more than 0,50 % .

4.12 Starch and dextrin

When tested according to 5.13 the solution shall not show any blue, violet, reddish or brownish colour.

4.13 Extractable colouring matter

When tested according to 5.14 the liquid obtained shall not be more intensely coloured than reference solution Y_5, GY_6 or a reference solution prepared as follows: to 3,0 ml of blue primary solution add 7,0 ml of hydrochloric acid (1 % m/V HCl) and dilute 0,5 ml of this solution to 10,0 ml with hydrochloric acid (1 % m/V HCl).

NOTE See annex A for reference solutions.

4.14 Loss on drying

When tested according 5.15 the loss of mass shall not be more than 8,0 %.

4.15 Sulphated ash

When tested according to 5.16 the amount of sulphated ash shall be as given in Table 3.

Table 3 — Sulphated ash for different materials

Material	Sulphated ash
Absorbent cotton gauze	shall not exceed 0,40 %
Absorbent cotton gauze Type 13 light	shall not exceed 0,75 %
Absorbent cotton and matt viscose ribbon gauze	shall not exceed 1,20 %
Absorbent cotton and lustrous viscose ribbon gauze	shall not exceed 0,45 %

5 Test methods

5.1 General

All tests shall be performed with the material in its final form i.e. sterile or non-sterile.

All reagents used shall be of analytical grade.

NOTE The preparation of test solution S is given in annex B.

5.2 Fibre identification

5.2.1 Absorbent cotton gauze and absorbent cotton ribbon gauze

5.2.1.1 Reagents

a) **Zinc chloride solution, iodinated**: Dissolve 20 g ± 0,5 g of zinc chloride and 6,5 g ± 0,1 g of potassium iodide in 10,5 ml ± 0,1 ml of water. Add 0,5 g ± 0,05 g of iodine and shake for 15 min. Filter if necessary. Store protected from light.

b) **Zinc chloride-formic acid solution**: Dissolve 20 g ± 0,5 g of zinc chloride in 80 g ± 1 g of an 85 % m/V solution of anhydrous formic acid.

5.2.1.2 Tests

Untwist a few threads in the warp and in the weft to free a few of the fibres to be examined and carry out IDENT tests A, B and C.

IDENT A: When examined under a microscope, the cotton fibre shall be flat, ribbon-like, 10 µm to 40 µm wide, with thickened ends and an irregularly shaped lumen.

IDENT B: When treated with iodinated zinc chloride solution, the fibres shall become violet.

IDENT C: To 0,1 g ± 0,05 g fibres add 10 ml ± 0,1 ml of zinc chloride-formic acid solution. Heat to 40 °C and allow to stand for 2,5 h, shaking occasionally.

5.2.2 Absorbent cotton and viscose ribbon gauze

5.2.2.1 Reagent

Hydrogen peroxide solution, dilute: Contains not less than 2,5 % m/m and not more than 3,5 % m/m of hydrogen peroxide in water.

5.2.2.2 Tests

Untwist a few threads in the warp and in the weft to free a few of the fibres to be examined and carry out IDENT tests A, B and C. The fibres from the warp shall comply with IDENT test A and C. The fibres from the weft shall comply with IDENT test B and C and where a mixture of fibres is present some of the fibres from the weft shall comply with IDENT test A.

IDENT A: Examined under a microscope, each cotton fibre shall consist of a single cell, up to about 40 mm long and up to 40 µm wide, in the form of a flattened tube with thick and rounded walls and often twisted.

IDENT B: The viscose fibres shall have an average length of 25 mm to 50 mm and when examined under a microscope in the dry state they shall be of uniform width; they shall be crimped and they shall have many longitudinal parallel lines distributed unequally over the width. The end-cuts shall be more or less straight. The surface of each fibre can be uneven, and the cross-section shall be approximately circular or elliptical, with a diameter of 10 µm to 20 µm. The matt fibres shall contain numerous granular particles of about 0,25 µm to 1 µm average diameter.

IDENT C: When treated with iodinated zinc chloride solution (5.2.1.1), the fibres shall become violet.

IDENT D: Dissolve the residue obtained in the test for sulphated ash (see clause 4.15) by warming gently with 5 ml ± 0,1 ml of sulphuric acid . Allow to cool and add 0,2 ± 0,01 ml of dilute hydrogen peroxide solution. The solution obtained from the product containing lustrous viscose shall undergo no change in colour; that from the product containing matt viscose shall show an orange-yellow colour, the intensity of which shall depend on the quantity of titanium dioxide present.

Note The residue from the test for sulphated ash can be yellowish in colour.

5.3 Test method for acidity or alkalinity

5.3.1 Reagents

a) **Phenolphthalein solution**. Dissolve 0,1 g ± 0,01 g of phenolphthalein solution in 80 ml of ethanol (containing 95,1 % to 96,9 % V/V ethanol) and make up to 100 ml with water.

b) **Methyl orange solution**. Dissolve 0,1 g ± 0,01 g of methyl orange in 80 ml ± 0,5 ml of water and make up to 100 ml ± 0,5 ml with ethanol (containing 95,1 % to 96,9 % V/V ethanol).

5.3.2 Test

To 25 ml ± 0,5 ml of solution S add 0,15 ml ± 0,01 ml of phenolphthalein solution and to another 25 ml ± 0,5 ml add 0,05 ml ± 0,001 ml of methyl orange solution.

Check for compliance with 4.2.

5.3.3 Tests for sensitivity.

a) To 0,1 ml ± 0,01 ml of the phenolphthalein solution add 100 ml ± 1 ml of carbon dioxide-free water. The solution shall be colourless. Not more than 0,2 ml of 0,02 N sodium hydroxide is required to change the colour to pink. Colour change: pH 8,2 (colourless) to pH 10,0 (red).

b) A mixture of 0,1 ml ± 0,01 ml of the methyl orange solution and 100 ml ± 1 ml of carbon dioxide-free water shall be yellow. Not more than 0,1 ml of 0,1 N hydrochloric acid is required to change the colour to red. Colour change: pH 3.0 (red) to pH 4.4 (yellow).

5.4 Test method for foreign fibres

When examined separately under a microscope, fibres from the warp shall be seen to consist exclusively or almost exclusively of cotton fibres and those from the weft exclusively or almost exclusively of typical viscose and/or cotton fibres. Occasionally for both fibres from the warp and from the weft, a few isolated foreign fibres may also be present.

5.5 Test method for fluorescence

When a two-ply layer is examined under ultraviolet light at 365 nm, it shall only display a slight brownish-violet fluorescence and a few yellow particles. With the exception of that shown by a few isolated fibres, no intense blue fluorescence shall be displayed

5.6 Test method for thread count

The test for the thread count shall be performed at a temperature of 20 °C ± 2 °C and having a relative humidity of 65 % r.h. ± 5 % r.h. after exposing the product for a minimum of 24 h to that atmosphere.

For absorbent cotton gauze count the number of threads in the warp and in the weft in a square piece with 100 mm sides well away from the edges. Repeat both counts twice in two different places, so that the three counts in both directions are well distributed over the sample to be tested.

The thread counts, calculated as the averages of the three individual counts, shall correspond to those given in Table 1 for the type of gauze to be examined.

For absorbent cotton and cotton and viscose ribbon gauze count the number of threads in the warp and in the weft over a length of 100 mm; if the width of the ribbon gauze is less than 100 mm count the number of threads over the whole of the width and calculate the number of threads per 100 mm on the basis of the declared width. If the width of the ribbon gauze is greater than 100 mm, do not include the selvedge in the count. Repeat both counts twice in two different places, so that the three counts in both directions are well distributed over the sample to be tested. The thread counts calculated as the averages of the three individual counts made in each direction shall correspond to those given in Table 2 for the type of ribbon gauze to be examined.

5.7 Test method for mass per square metre

The test for the mass per square metre shall be performed at a temperature of 20 °C ± 2 °C and having a relative humidity of 65 % r.h. ± 5 %r.h. after exposing the product for a minimum of 24 h to that atmosphere.

Weigh a piece of absorbent cotton gauze exactly 1 m in length using the full width or, for smaller dressings, pieces not less than 2.5 dm^2 given a total surface of at least 50 dm^2. Calculate the mass per square metre. It shall not be less than the value given in Table 1 for the type of gauze to be examined.

Determine the mass of the whole absorbent cotton or cotton and viscose ribbon gauze and calculate its area by multiplying the nominal width by the length, measured on the unrolled gauze under slight tension along the centre. Calculate the mass per square metre. The value obtained shall not be less than the value shown in Table 2 for the type of ribbon gauze to be examined.

5.8 Test method for minimum breaking load

5.8.1 Absorbent cotton gauze

Prepare ten pieces, five cut in the direction of the weft and five in the direction of the warp not less than 15 mm from the edges, avoiding folded or fraying areas. Each piece shall be 50 mm wide and sufficiently long to allow the clamps of the machine to be 200 mm apart when the piece is inserted. Clamp each piece in turn between the jaws of a constant-rate-of-traverse machine and apply a speed of movement of 100 mm ± 10 mm per min.

Check for the average value obtained on each group of five samples to be in compliance with 4.7.

5.8.2 Absorbent cotton ribbon gauze and absorbent cotton and viscose ribbon gauze

For ribbon gauze of width greater than 50 mm make two cuts parallel to the selvedges so as to obtain from the centre of the ribbon pieces at least 60 mm wide. Remove warp threads from the two sides so as to leave fringes about 5 mm long and obtain a width of the remaining warp threads of exactly 50 mm. For ribbon gauze 50 mm or less in width, test the sample using the full width and calculate with respect to a 50 mm width. Prepare five pieces of ribbon gauze of sufficient length to allow distance between the clamps of the machine to be 200 mm. Clamp each piece in turn between the jaws of a constant rate-of-traverse machine and apply a speed of movement of 100 mm ± 10 mm per min.

Check for the average value obtained on each group of five samples to be in compliance with 4.7.

5.9 Test method for sinking time

Fill a beaker of 110 mm to 120 mm in diameter to a depth of 100 mm ± 10 mm with water at 20 ºC ± 2 ºC. By means of forceps fold a piece of gauze weighing about 1 g four times (i.e. into sixteen folds) and smooth the surface. For narrow ribbon gauze, fold as many times as is necessary to obtain a length not greater than 80 mm.

Allow the gauze to drop lightly upon the surface of the water.

Measure with a stopwatch the time taken by the gauze to sink below the surface of the water. Calculate the results as the average of three tests.

Check for compliance with 4.8.

5.10 Test method for ether soluble substances

In a continuous extraction apparatus, extract 5,00 g of gauze with diethyl ether for 4 h at the rate of at least four extractions per hour. Evaporate the ether extract and dry the residue to constant mass at 100 ºC to 105 ºC.

Check for compliance with 4.9.

5.11 Test method for surface active substances

Introduce 10 ml of the solution prepared to produce solution S (see annex B) into a graduated ground glass-stoppered cylinder with an external diameter of 20 mm ± 2 mm, previously rinsed with sulphuric acid and then water. Shake vigorously thirty times in 10 s, allow to stand for 1 min and repeat the shaking. After 5 min, the height of the froth above the liquid shall be measured.

Check for compliance with 4.10.

5.12 Test method for water-soluble substances

Boil 7,00 g ± 0,1 g of gauze in 700 ml ± 10 ml of water for 30 min, stirring frequently and replacing the water lost by evaporation. Decant the liquid, squeeze out the residual liquid from the material with a glass rod and mix. Reserve 200 ml of the liquid for the test for starch and dextrin (see 4.12) and filter the remainder whilst hot. Evaporate 400 ml of the extract (corresponding to $4/7^{th}$ of the mass of the sample taken) and dry the residue to constant mass at 100 ºC to 105 ºC. Calculate the residue based on the actual weights.

Check for compliance with 4.11.

5.13 Test method for starch and dextrin

Allow 200 ml of the unfiltered extract reserved in the test for water soluble substances (5.12) to cool and add 5 ml of acetic acid and 0,15 ml of 0,1 N iodine solution.

Check for compliance with 4.12.

5.14 Test methods for extractable colouring matter

The examination of the degree of coloration of liquids in the range brown-yellow-red shall be carried out by using identical tubes of colourless, transparent neutral glass with a flat base and an internal diameter of 15 mm to 25 mm. Compare the liquid to be examined with water or the solvent or the reference solution, the depth of the layer being 40 mm ± 2 mm. Compare the colours in diffused daylight, viewing vertically against a white background.

NOTE See annex A for reference solutions to determine the degree of coloration of liquids.

5.15 Test method for loss on drying

Weigh the sample of approximately 5 g (W_1) to an accuracy of two digits. Place the sample in a preheated oven set at 100 ºC to 105 ºC and wait for 30 min. Take the sample from the oven by appropriate means. Wait for 5 min and weigh the sample to an accuracy of two digits (W_2) Calculate the loss of mass as a percentage by the following formula: $\{(W_1 - W_2) / W_1\} * 100$.

Check for compliance with 4.14.

5.16 Test method for sulphated ash

Introduce 5,00 g of the gauze into a previously heated and cooled, tared crucible. Heat cautiously over a naked flame and then carefully to dull redness at 600 ºC. Allow to cool, add a few drops of dilute sulphuric acid, heat and incinerate until all the black particles have disappeared. Allow to cool. Add a few drops of ammonium carbonate solution. Evaporate and incinerate, allow to cool and weigh again. Repeat the incineration for periods of 5 min until a constant mass is attained.

Check for compliance with 4.15.

6 Test report

The report shall include at least the following information:

a) type of material/product, including lot number;

b) any deviations from the test method;

c) individual and average results;

d) date of test;

e) identity of the person(s) who carried out the test.

Annex A
(normative)

Reagents to determine the degree of coloration of liquids

A.1 Primary solutions

A.1.1 Yellow solution

Dissolve 46,0 g of ferric chloride in about 900 ml ± 10 ml of a mixture of 25 ml of hydrochloric acid and 975 ml of water and make up to 1000,0 ml with the same mixture. Titrate, and adjust the solution to contain 45,0 mg of $FeCl_3 \cdot 6H_2O$ per ml by adding the same acid mixture. The solution shall be protected from light.

Titration: Place in a 250 ml conical flask fitted with a ground-glass stopper, 10,0 ml ± 0,2 ml of the solution, 15 ml ± 0,2 ml of water, 5 ml ± 0,2 ml of hydrochloric acid and 4 g of potassium iodide, close the flask, allow to stand in the dark for 15 min and add 100 ml ± 5 ml of water. Titrate the liberated iodine with 0,1 N sodium thiosulphate, using 0,5 ml ± 0,05 ml of starch solution, added towards the end of titration, as indicator.

1 ml of 0,1 N sodium thiosulphate is equivalent to 27,03 mg of $FeCl_3 \cdot 6H_2O$.

A.1.2 Red solution

Dissolve 60 g ± 1 g of cobalt chloride in 900 ml ± 10 ml of a mixture of 25 ml ± 0,5 ml of hydrochloric acid and 975 ml ± 5 ml of water and make up to 1000 ml with the same mixture. Titrate, and adjust the solution to contain 59,5 mg of $CoCl_2.6H_2O$ per ml by adding the same acid mixture.

Titration: Place in a 250 ml conical flask with a ground-glass stopper, 5,0 ml ± 0,2 ml of the solution, 5 ml ± 0,02 ml of dilute hydrogen peroxide solution and 10 ml ± 0,5 ml of a 30 % *m/V* solution of sodium hydoxide. Boil gently for 10 min, allow to cool and add 60 ml ± 1 ml of dilute sulphuric acid and 2 g ± 0,1 g of potassium iodide. Close the flask and dissolve the precipitate by shaking gently. Titrate the liberated iodine with 0,1 N sodium thiosulphate, using 0,5 ml ± 0,05 ml of starch solution, added towards the end of the titration, as indicator. The end-point is reached when the solution turns pink.

1 ml of 0,1 N sodium thiosulphate is equivalent to 23,79 mg of $CoCl_2.6H_2O$.

A.1.3 Blue primary solution

Dissolve 63 g ± 1 g of copper sulphate in 900 ml ± 10 ml of a mixture of 25 ml ± 0,2 ml of hydrochloric acid and 975 ml ± 10 ml of water and make up to 1000,0 ml with the same mixture. Titrate, and adjust the solution to contain 62,4 mg of $CuSO_4 \cdot 5\ H_2O$ per ml by adding the same acid mixture.

Titration: Place in a 250 ml conical flask fitted with a ground-glass stopper, 10,0 ml ± 0,2 ml of the solution, 50 ml ± 0,2 ml of water, 12 ml ± 0,5 ml of dilute acetic acid and 3 g of potassium iodide. Titrate the liberated iodine with 0,1 N sodium thiosulphate, using 0,5 ml ± 0,05 ml of starch solution, added towards the end of the titration, as indicator. The end-point is reached when the solution shows a slight pale brown colour.

1 ml of 0,1 N sodium thiosulphate is equivalent to 24,97 mg of $CuSO_4 \cdot 5\ H_2O$.

A.2 Standard solutions

Using the three primary solutions, prepare the five standard solutions as follows.

Table A.1 — Standard solutions

	Volume in ml			
Standard solution	**Yellow solution**	**Red solution**	**Blue solution**	**Hydrochloric acid (1 % *m/V* HCl)**
B (brown)	3,0	3,0	2,4	1,6
BY (brownish-yellow)	2,4	1,0	0,4	6,2
Y (yellow)	2,4	0,6	0	7,0
GY (greenish-yellow)	9,6	0,2	0,2	0
R (red)	1,0	2,0	0	7,0

A.3 Reference solutions

Using the five standard solutions, prepare the following reference solutions.

Table A.2 — Reference solutions B

	Volume in ml	
Reference solution	**Standard solution B**	**Hydrochloric acid (1% *m/V* HCl)**
B_1	75,0	25,0
B_2	50,0	50,0
B_3	37,5	62,5
B_4	25,0	75,0
B_5	12,5	87,5
B_6	5,0	95,0
B_7	2,5	97,5
B_8	1,5	98,5
B_9	1,0	99,0

Table A.3 — Reference solutions BY

	Volume in ml	
Reference solution	**Standard solution BY**	**Hydrochloric acid (1% m/V HCl)**
BY_1	100,0	0
BY_2	75,0	25,0
BY_3	50,0	50,0
BY_4	25,0	75,0
BY_5	12,5	87,5
BY_6	5,0	95,0
BY_7	2,5	97,5

Table A.4 — Reference solutions Y

	Volume in ml	
Reference solution	**Standard solution Y**	**Hydrochloric acid (1% m/V HCl)**
Y_1	100,0	0
Y_2	75,0	25,0
Y_3	50,0	50,0
Y_4	25,0	75,0
Y_5	12,5	87,5
Y_6	5,0	95,0
Y_7	2,5	97,5

Table A.5 — Reference solutions GY

	Volume in ml	
Reference solution	**Standard solution Y**	**Hydrochloric acid (1% m/V HCl)**
GY_1	25,0	75,0
GY_2	15,0	85,0
GY_3	8,5	91,5
GY_4	5,0	95,0
GY_5	3,0	97,0
GY_6	1,5	98,5
GY_7	0,75	99,25

Annex B
(normative)

Preparation of test solution S

Place 15,0 g of the material in a suitable vessel, add 150 ml of water, close the vessel and allow to macerate for 2 h. Decant the solution, squeeze the residual liquid from the sample with a glass rod into the decanted solution and mix. Reserve 10 ml of the unfiltered solution for the test for surface active substances (clause 4.10) and filter the remainder.

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

This European standard 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 93/42/EEC.

WARNING : Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93.42/EEC	Comments
4	1, 2, 3, 4, 7.1, 7.2, 7.3	Addresses first phrase of 7.3 (i.e. as far as the semi-colon)
5	1, 2, 3, 4, 7.1, 7.2, 7.3	Addresses first phrase of 7.3 (i.e. as far as the semi-colon)

blank

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