BS EN 16128:2025

BSI Standards Publication

Ophthalmic optics — Reference method for the testing of spectacle frames and sunglasses for nickel release

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National foreword

This British Standard is the UK implementation of EN 16128:2025. It supersedes BS EN 16128:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/3, Spectacles.

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

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English Version

Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release

Optique ophtalmique - Méthode d'essai de référence relative à la libération du nickel par les montures de lunettes et les lunettes de soleil

Augenoptik - Referenzverfahren für die Bestimmung der Nickellässigkeit von Brillenfassungen und Sonnenbrillen

This European Standard was approved by CEN on 8 September 2025.

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European foreword

This document (EN 16128:2025) has been prepared by Technical Committee CEN/TC 170 “Ophthalmic optics”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2026, and conflicting national standards shall be withdrawn at the latest by April 2026.

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

This document supersedes EN 16128:2015.

EN 16128:2025 includes the following significant technical changes with respect to EN 16128:2015:

— Clause 4 has been modified to give a better scientific explanation of why a sample that fails the coating test might pass the migration test. It also states that the coating test is not a screening test since a pass allows a product to be labelled as compliant with REACH. A revised flowchart (Figure 1) reinforces this. The warning about taking particular attention over handling samples to avoid additional damage has been reinforced;

— Clause 5 emphasizes that if a sample fails the coating test, then all parts of the sample have to be tested with the migration test, not just the part that failed;

— Clause 6 notes that the lenses are needed in the frame to protect the groove during the simulated wear and corrosion procedure. Although it applies to EN 12472, new Annex A provides illustrations of mounts that can be used to hold sample frames in the tumbling barrel;

— Clauses 7 and 8 refer to the new normative Annex B for advice on where to test sides. Both recommend that the test or dummy lenses are kept in the frame for the tests;

— More detailed advice on where to mask frames before the coating test has been provided in Clause 7. The new quality control samples are mentioned in the new Annex D. Photographic records of the samples are now required in the test report;

— Clause 8 now permits the use of a hermetically-sealed cabinet and laboratory oven to be used for the migration process as well as a climate chamber. The concentration of the control solution has been doubled and the volume halved, to avoid overloading the piece of test paper, which is suggested to be 10 % larger. Again, photographic records of the samples are now required in the test report;

— Annexes B, C and D have photographic figures to illustrate sample preparation since they give better clarity than drawings. The examples pictured provide no manufacturer markings and are in no way intended to promote a particular manufacturer or style;

— Annex E has been revised to recommend folding of the sealing film over the test or dummy lenses rather than wrapping around the rim.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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Introduction

This document has been prepared under Mandate M/448 issued by the European Commission in the framework of Regulation (EC) No 1907/2006, REACH, in particular Commission Regulation (EC) No 552/2009 of 22 June 2009 amending regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and restriction of Chemicals (REACH) as regards Annex XVII RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES.

The aim of the mandate was the development of a new method of analysis to detect the release of nickel from spectacle frames and sunglasses.

The availability of the new reference method for the determination of the release of nickel will provide the reliable framework to enforce the limit value for nickel release set forth by the European Regulation of 0,5 $\mu g \cdot cm^{-2} \cdot week^{-1}$ (expressed as 0,5 $\mu g/cm^2/week$ in the Regulation). It will ensure a uniform application and control of the European legislation in all member states.

Harmonizing the test method for nickel release in all member states is vital with a view to protecting effectively the health of the end consumer, that is, the spectacle wearer. Nickel allergy is still the most frequent contact allergy in Europe and a significant health issue.

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1 Scope

This document specifies the reference method for the testing of spectacle frames, ready-to-wear near-vision spectacles, sunglasses and spectacle frames used for eye and face protection for nickel release.

The reference method supports the demonstration of conformity with the limit value for nickel release of 0,5 $\mu g \cdot cm^{-2} \cdot week^{-1}$ set forth by European Regulation.

The reference method involves the procedural steps shown in Figure 1 and described in Clause 4.

This document applies to those parts of metal spectacle frames and those metal parts of combination spectacle frames that are intended to come into direct and prolonged contact with the skin of the wearer. This document also applies to those relevant metal parts of ready-to-wear near-vision spectacles, sunglasses and spectacle frames used for eye and face protection.

NOTE The reference method for articles apart from spectacle frames, ready-to-wear near-vision spectacles, sunglasses and spectacle frames used for eye and face protection is specified in EN 1811.

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.

EN 12472, *Method for the simulation of accelerated wear and corrosion for the detection of nickel release from coated items*

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

EN ISO 7998:2005, *Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary (ISO 7998:2005)*

EN ISO 12870:2025, *Ophthalmic optics — Spectacle frames — Requirements and test methods (ISO 12870:2024)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 12870:2025, EN ISO 7998:2005 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
model
spectacle frame, ready-to-wear spectacles, sunglass or other item used for eye and face protection produced to the same design, using the same materials and surface treatment, and to which the scope of this document applies

3.2
test sample
spectacle frame, ready-to-wear spectacles, sunglass or other item used for eye and face protection submitted for testing

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3.3
test part
part of a test sample that is intended to come into direct and prolonged contact with the skin and therefore requires testing

Note 1 to entry: These parts are defined in 7.3.1 (for the coating test) and in 8.3.1 (for the migration test).

3.4
test paper
piece of laboratory cellulose paper used for testing, at any stage of the procedure after being cut to size for testing

3.5
extraction solution
solution obtained after extraction of nickel ions from the test paper

3.6
appropriate tool
tool enabling the procedure to be performed without causing contamination by nickel or other metal ions, either from the material of the tool or deposits on it

Note 1 to entry: Such tools could be made from plastics, titanium, or stainless steels.

3.7
appropriate equipment
equipment enabling the procedure to be performed without causing contamination by nickel or other metal ions, either from the material of the equipment or deposits on it

3.8
electrically non-conductive coated part
part of a test sample that has a covering, on a substrate, that does not conduct an electrical current and has protective and/or decorative properties

Note 1 to entry: These non-conductive coatings/coverings are generally based on organic polymers.

4 Principle

Following the simulation of wear and corrosion according to the method specified in EN 12472 (see Clause 6), the reference method comprises the following two tests:

1) Coating test, applicable only to test parts with an electrically non-conductive coating, based on Electrochemical Impedance Spectroscopy (EIS) and specified in Clause 7. Its aim is to demonstrate the ability of the electrically non-conductive coating to limit any release of metal ions from the test sample substrate as indicated by the impedance threshold, thereby ensuring that the nickel release from the test sample does not exceed the regulatory limit. The coating test is a test of the ability of the electrically non-conductive coating to prevent the release of metal ions from the substrate of the test sample. A pass in this test can be used to claim compliance with REACH.

2) Migration test for nickel ion release, specified in Clause 8, is a quantitative test to determine whether or not the nickel release from the model exceeds the regulatory limit. The migration test comprises two steps: Release of nickel by artificial sweat solution into a test paper and the subsequent quantitative analytical detection of the nickel released into the paper.

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Figure 1 illustrates the relationship between the two tests; the coating test is not a screening test since a pass allows a product to be labelled as compliant with REACH. In addition to frames without an electrically non-conductive coating, the coating test cannot be applied to the following for technical reasons: very small components (e.g. screw heads, trims on sides, side tips or fronts – see 8.3.2) and frames fitted with magnets (e.g. to hold clip-ons).

Metal frames that are uncoated (i.e. neither organic coated nor metal plated) and made of homogeneous alloys or metals do not require the simulation of wear and corrosion specified in Clause 6 and shall be tested directly in accordance with Clause 8. Unless the manufacturer certifies that a component is homogeneous and uncoated, the component shall be assumed to be coated.

If a part of the sample fails the coating test, that part of the same test sample can be retested with the coating test (7.5.3).

In general, it is recommended that all suitable frames should be tested with the coating test, and only those that are unsuitable or fail the coating test be subject to the migration test. The laboratory's client is, however, not restrained from preferring to test frames directly with the migration test, provided the request is provided in writing to the laboratory.

If a sample fails the coating test and the laboratory's client wishes to proceed further with testing, either new test samples or, subject to the requirements of the laboratory's client, the original test samples shall be subjected to the migration test in order to verify whether nickel ions are subsequently released and to obtain a quantitative value. For example, a thin coating on a substrate (such as a titanium alloy) that does not release nickel might fail the coating test but pass the migration test.

Requirements for sampling and guidance as to which parts of the test samples shall be subject to testing (the test parts) are given in Clause 5 and in 7.3.1 (for the coating test) and 8.3.1 (for the migration test).

WARNING — Test laboratories shall pay particular attention to the careful handling of test samples and test parts during all stages of this standard, using appropriate tools when needed. Poor handling, particularly when dismantling or cutting a test sample, may cause additional damage that causes a failure.

5 Selection of test samples

The laboratory's client should select, at random, two representative specimens of each model to be tested for either the coating or the migration test.

The selected specimens shall be labelled, e.g. by allocating them a laboratory code or number for identification.

Test samples used for the coating test can be tested in a subsequent migration test, but test samples used for the migration test cannot be tested in a subsequent coating test.

If a test sample is likely to be subjected to the migration test after the coating test, it shall be washed thoroughly in deionized water immediately after the coating test and allowed to dry to avoid corrosion from sodium chloride.

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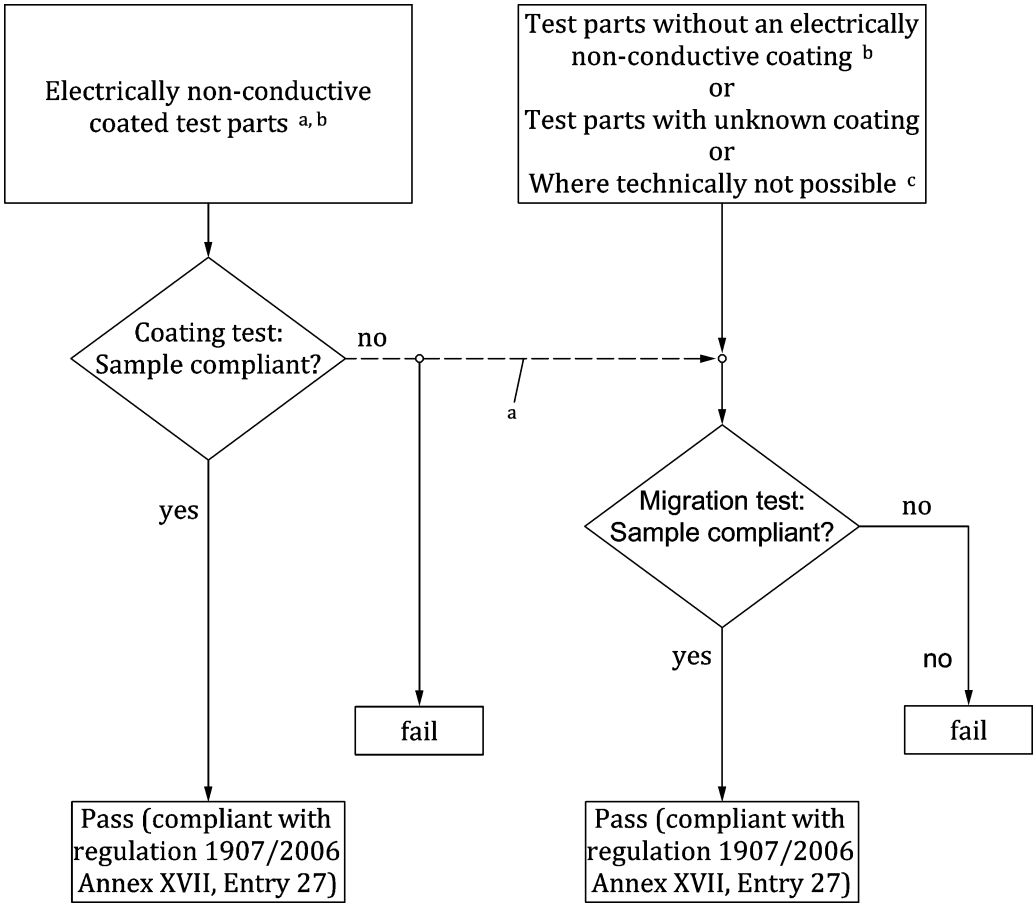

Key

a The coating test is a test of the ability of the electrically non-conductive coating to prevent the release of metal ions from the substrate of the test sample. If a sample fails the coating test and the laboratory's client wishes to proceed further with testing, the samples or new samples shall be subjected to the migration test in order to verify whether nickel ions are subsequently released and to obtain a quantitative value. See Clause 4.

b On the request of the laboratory's client, test samples can be tested directly using the migration test, but the extra information about the coating that is obtained by using the coating test will be unknown.

c The coating test cannot be used to test very small components, e.g. screw heads, trims on sides, side tips or fronts. It also cannot be used with frames fitted with magnets, e.g. to hold clip-ons.

If a sample fails, conductivity of parts not in contact with the skin (for example, trims) shall be verified using an electric circuit tester and shall be masked if uncoated.

Figure 1 — Diagrammatic overview of the reference test method

6 Simulation of wear and corrosion

6.1 Preparation of test samples

Samples should be fitted with test lenses, which should preferably be supplied or specified by the laboratory's client, i.e. the manufacturer or importer or authorized representative.

NOTE 1 The lenses protect the edges of the groove, so that testing without lenses can cause a false failure.

If the client agrees, then the dummy or demonstration lenses can be used.

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NOTE 2 The greater thickness of organic prescription spectacle lenses can give superior protection to the edge of the groove than a dummy or demonstration lens.

If test lenses are not supplied or specified, then the testing laboratory shall contact the frame manufacturer for a recommendation for the test lens's material, power, thickness, curvature and, as appropriate, bevel angle or edge profile.

In the absence of supply or specifications from the manufacturer or an inability to contact the manufacturer, test lenses are recommended to be of suitable material for the type of frame and have a vertex power of (0,00 ± 0,25) D, a centre thickness of (2,00 ± 0,20) mm and a curvature appropriate for the frame.

For all test samples, sides and fronts shall be separated from each other. Sides shall be dismantled from fronts, either by unscrewing the dowel (hinge) screw or by cutting the joint across the charniers (leaves of the hinge).

Unless they have a metal-bearing surface, nose pads shall be removed. To avoid subsequent difficulties with masking the pad box for the coating test, it is recommended that, except for frames fitted with pads having a metal-bearing surface, the pads be removed by cutting off the pad arms complete with the pad box and pads, see 7.3.2.

Removing end covers (side tips) from sides is optional.

Ensure that all the separate test parts remain identified throughout all steps of the overall procedure.

6.2 Procedure

Except for components that are certified by the manufacturer to be homogenous and uncoated, perform the simulation of wear and corrosion according to EN 12472. Ensure that the paste is not used after its shelf life has expired.

NOTE Fronts can conveniently be clamped by means of the dummy or test lenses, and sides on the part that is covered by the end cover (temple tip). See Annex A. EN 12472 specifies that the back surface of the front and inside of the sides face towards the axis of the assembly.

When the simulation is completed, remove the test samples. Gently swirl them for 2 min in degreasing solution (see 7.2.4) at room temperature. Rinse thoroughly with deionized water. Gently dry in a clean air stream or allow to dry on absorbent paper.

After degreasing, handle the test samples with appropriate tools or clean laboratory gloves.

Disassemble three-piece rimless fronts. Disassemble fronts of combination frames and remove any plastic parts.

Then subject the test parts to the selected test: coating test, see Clause 7, and/or migration test, see Clause 8.

7 Coating test

7.1 General

The purpose of the coating test is to verify whether the surface treatment of a model is able to limit sufficiently the release of metal ions (including nickel), as indicated by the impedance threshold limit. Test samples that are not identified as “pass” can be retested if 7.5.3 applies or be subjected to the migration test, see Clauses 4 and 5.

The parts of test samples needing consideration are only those intended to come into direct and prolonged contact with the skin of the wearer, see 7.3.1.

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7.2 Apparatus and consumables

7.2.1 Masking agent, suitable for electroplating purposes and capable of electrically insulating the test part from the saline solution. Application of more than one coat is acceptable and can be preferable.

Test the masking agent to verify that it is suitable by using it to coat a metal strip without an organic coating and show that the adhesion is good and impedance results are high (greater than $5{,}0 \cdot 10^6\ \Omega \cdot cm^2$).

NOTE 1 A metal strip with approximate dimensions of 2 mm thick, 6 mm wide, and 100 mm long is suitable.

It is useful if the masking agent is coloured or fluorescent, to make the masked areas more visible.

NOTE 2 Lacomit is the trade name of a suitable product.[1)]

7.2.2 Deionized water, according to EN ISO 3696, grade 3 or to European Pharmacopoeia, for rinsing and preparation of the saline solution (7.4).

7.2.3 Sodium chloride of recognized pro analysis, p.a. grade or better, for preparation of the saline solution (7.4).

7.2.4 Degreasing solution, to clean the test samples after cutting, etc. and before testing. Dissolve 5 g of an anionic surface-active agent such as sodium dodecylbenzene sulfate or sodium alkylaryl sulfate in 1 000 ml deionized water (7.2.2). An appropriately diluted, neutral, commercially available detergent can also be used.

7.2.5 Apparatus for preparation of 1 % saline solution in deionized water.

7.2.6 Electro-chemical cell, made of glass, suitable for mounting firstly a Standard Calomel (SCE) or Ag/AgCl Reference Electrode, secondly a Graphite or Platinum Counter Electrode and thirdly, the test part.

The recommended counter electrode is a high-density pure graphite rod, approximately 6 mm in diameter.

7.2.7 Laboratory clamps, suitable for holding the test part, with the selected area immersed in the electrolyte in the electro-chemical cell, but with the electrical contact area kept dry.

7.2.8 Potentiostat, having the ability to perform A.C. Electrochemical Impedance Spectroscopy (EIS) at 1 Hz and having a current sensitivity of better than 1 pA.

NOTE An example of suitable apparatus is Gamry apparatus Interface 1010B package.[2)]

7.2.9 Electrical clamps, e.g. small crocodile clips, capable of providing secure electrical contact with the test part, reference and counter electrodes.

7.2.10 Calibration (dummy) cell, usually supplied by the potentiostat manufacturer together with the instrument, appropriate to test the potentiostat in the impedance range expected.

[1)] Lacomit is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of this product. Equivalent products can be used if they can be shown to lead to the same results.

[2)] Gamry apparatus Interface 1010B is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of this product.

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7.2.11 Appropriate tools, needed to perform the procedure. See 3.6 for the definition of "appropriate tools". To prevent possible contamination by nickel or other metal ions, clean all tools well before and after use.

7.2.12 Laboratory gloves, e.g. latex or PVC, but not cotton.

7.2.13 Faraday cage; either an earthed Faraday cage, earthed aluminium foil or earthed conductive cloth to house the electro-chemical cell during measurement.

7.3 Preparation of test samples for the coating test

7.3.1 Parts to be tested

See Clause 5 for sampling requirements.

For testing of models with the coating test, the parts to be tested are:

a) the front, comprising the rims, the bridge and, if applicable, the brace bar but excluding the pad arms and pad boxes, lugs and, if temporal, closing block joints;

b) sides (temples), including metal collets, but excluding those areas intended to be protected by plastic end covers (tips). Joints and the zone immediately around them are excluded unless they are in the zone to be tested. Sides shall be tested in the areas specified in Annex B.

Nose pads with metal-bearing surfaces shall be tested using the migration method in Clause 8.

For each of the two test samples, the front and the two sides shall be tested separately; all three parts of both test samples shall pass in order for the model to pass.

7.3.2 Dismantling and/or cutting and/or masking

7.3.2.1 General

Prior to submission to the coating test, the test sample shall have been subject to the method for simulation of wear and corrosion according to EN 12472. See Clause 6.

After completion of the simulation of wear and corrosion, select and separate those parts (or areas) that are subject to the coating test from those that are not. This can be achieved by one or more of the following:

a) dismantling (see 7.3.2.2);

b) cutting (see Annex C);

c) masking (see 7.3.2.3 and Annex C).

The dummy or test lenses needed for the simulation of wear and corrosion (see 6.1) shall be left in the front.

NOTE 1 Removing dummy or demonstration lenses by pushing them out without opening the closing block (lens retaining) joint risks damaging the coating on the inside of the rims.

Consider the need for preparing the electrical contact area (see 7.3.4) and for determination of surface area (see 7.3.3) when deciding where to cut or which areas to mask. Masking any "complicated" details of the test sample that would not come into direct and prolonged contact with the skin could simplify the determination of surface area and/or enhance its precision.

Cutting of the test samples except across the charniers and pad arms (see 6.1), to separate the parts (or areas) to be tested from those not to be tested, is permissible but should be avoided if at all possible.

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NOTE 2 Cutting can be avoided by masking the entire test part except those parts (or areas) to be subjected to the test.

CAUTION — If cutting is undertaken, great care shall be taken to avoid contamination by metal ions e.g.:

— from the base material;

— from metal particles getting underneath the masking;

— by damaging the organic coating that is near the cut and subsequently tested;

— from metal on tools or fingers or the work area.

Ensure that all the separate parts of the test samples remain identified, e.g. assign identification numbers or codes, while not physically touching or modifying them.

7.3.2.2 Dismantling

Nose pads with metal-bearing surfaces shall be dismantled from fronts as they need to be tested according to Clause 8.

7.3.2.3 Masking

Gently swirl the test sample(s) for 2 min in degreasing solution (7.2.4) at room temperature. Rinse thoroughly and carefully with deionized water (7.2.2) and gently dry in a clean air stream or allow to dry on absorbent paper.

NOTE This cleaning stage is intended to remove plasticizers from packaging, extraneous grease and skin secretions due to handling, but not any protective coatings.

After degreasing, handle the test samples with appropriate tools or clean laboratory gloves.

Masking can be done by dipping, using a dispenser[3)] with a syringe having a fine needle or painting, either with a brush or with a dental plugger. Whichever method is used, ensure that the resulting masking film is much thicker than, e.g. twice as thick as, the original coating of the test sample or the part thereof. Ensure that cut edges are covered. Dip or paint/brush twice, allowing approximately 30 min between the applications. After allowing the masking agent to dry for a minimum of 15 min, inspect the quality of masking visually with a low-powered (e.g. 2x to 5x) magnifier to ensure complete coverage of the appropriate areas. If required, apply an additional layer(s) of masking agent. See Annex C for details.

Closing blocks, if temporal, including their screws shall be masked, if intended to be immersed. Closing block joints situated elsewhere on the rim so that they could come into prolonged contact with the skin, e.g. nasally, shall not be masked and shall be subjected to the coating test.

The grooves of rims do not need masking, but they can be masked during this process in areas adjacent to lugs and where pad arms had been attached. If, however, the frame has been submitted to the simulation of wear test (6.2) without lenses, the groove shall be masked.

Mask all soldered joints that will be immersed in the saline cell, e.g. mask the areas where the bridge and bracebar, if fitted, is soldered to the rims.

Other parts to be masked can depend upon the choice of electrical contact area and whether or not the test sample is cut.

[3)] A mechanised syringe can be helpful, e.g. the Chimetic Dosatore CH/N24V from http://www.chimitec.com/dosatrici_uk.htm. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of this product. Equivalent products can be used if they can be shown to lead to the same results.

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