

TECHNICALST CONSTRUTION FILE

Report Reference No. SHJDT/6D0325-GPSD

Applicant: Qingdao Tide Sports Products Co.,Ltd.

Address: 115# Xianggongshan Road, Binhai Street, Huangdao Zone,
Qingdao City, China.

Manufacturer: Qingdao Tide Sports Products Co.,Ltd.

Address: 115# Xianggongshan Road, Binhai Street, Huangdao Zone,
Qingdao City, China.

Sample Name: Mouthguards

Model: EVA QTMG001-QTMG100,Silicone QTSG001-QTSG100,TPR
QTTG001-QTTG100

Standard: EN1186-1:2002; EN 957-1:2005

Test Period: Mar.15, 2022 to Mar.26, 2022

Test Result: Please refer to next pages

Conclusion: Based on the performed tests on submitted samples, the results comply with the Low Voltage Directive 2014/35/EU and its subsequent amendments

Tested By: 

John Xia - Engineer

Reviewed By: 

Amy Li - Lab Manager

| | | |
|--|---|--|
| Applicant | Qingdao Tide Sports Products Co.,Ltd. | |
| Address | 115# Xianggongshan Road, Binhai Street, Huangdao Zone, Qingdao City, China. | |
| Test Item Description | | |
| Product Name : | Mouthguards | |
| Standard : | EN1186-1:2002; EN 957-1:2005 | |
| Model/Type Reference : | EVA QTMG001-QTMG100,Silicone QTSG001-QTSG100,TPR QTTG001-QTTG100 | |
| Test Case Verdicts | | |
| Test case does not apply to the test object : | N(.A .) | |
| Test item does meet the requirement : | P(ass) | |
| Test item does not meet the requirement : | F(ail) | |
| General Remarks | | |
| <ul style="list-style-type: none"> ◆ This report shall not be reproduced except in full without the written approval of the testing laboratory. ◆ The test results presented in this report relate only to the item tested. ◆ Clause numbers between brackets refer to clauses in EN 417:2012. ◆ “(see remark #)”refers to a remark appended to the report. ◆ “(see Annex #)”refers to an annex appended to the report. ◆ Throughout this report a point is used as the decimal separator. | | |

| Clause | Requirement - test | Result-Remark | Verdict |
|-------------|--|---------------|----------|
| 3 | Terms and definitions | | - |
| 3.1 | plastics | | - |
| 3.2 | final article article in its ready-for-use state or as sold | | P |
| 3.3 | sample material or article under investigation | | P |
| 3.4 | test specimen portion of the sample on which a test is performed | | P |
| 3.5 | test piece portion of the test specimen | | P |
| 3.6 | conventional oven oven where the air within the oven is heated and this heat is then transferred to the food through the plastic as opposed to a microwave oven where the food itself is heated directly by microwave irradiation | | - |
| 3.7 | food simulant medium intended to simulate a foodstuff (see clause 3 and clause 4) | | P |
| 3.8 | migration test test for the determination of overall migration using food | | P |
| 3.9 | substitute test test carried out which uses test media under conventional substitute test conditions when the use of migration tests | | P |
| 3.10 | test media substances used in "substitute tests", iso-octane, 95 % ethanol in aqueous solution and modified polyphenylene oxide | | P |
| 3.11 | alternative test tests, with volatile media, that may be used instead of migration tests with fatty food simulants | | P |
| 3.12 | extraction tests tests in which media having strong extraction under very severe test conditions are used | | P |
| 3.13 | overall migration, global migration mass of material transferred to the food simulant or test media as determined by the relevant test method | | P |
| 3.14 | overall migration, global migration mass of material transferred to the food simulant or test media as determined by the relevant test method | | P |
| 3.15 | pouch receptacle of known dimensions manufactured from film to be tested, which when filled with food simulant exposes the food contact side of the film to the food simulant or test medium | | - |

| | | | |
|------------|--|--|---|
| 3.16 | reverse pouch pouch which is fabricated such that the surface intended to come into contact with foodstuffs is the outer surface. All of its sides are sealed to prevent the inner surfaces coming into contact with the food simulant. The reverse pouch is intended to be totally immersed in food simulant or test medium | | - |
| 3.17 | cell device in which a film to be tested can be mounted which, when assembled and filled with food simulant, exposes the food contact side of the film to the food simulant or test medium | | P |
| 3.18 | repeatability value 'r' value below which the absolute difference between two single test results obtained under repeatability conditions may be expected to lie with a probability of 95 % | | - |
| 3.19 | reproducibility value 'R' value below which the absolute difference between two single test results obtained under reproducibility conditions may be expected to lie with a probability of 95 % | | P |
| 3.20 | repeatability conditions conditions where mutually independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time | | P |
| 3.21 | reproducibility conditions conditions where test results are obtained with the same method on identical material in different laboratories with different operators using different equipment | | - |
| | Other capacities, dimensions and shapes of pierceable cartridges are permitted, provided that they cannot be fitted into and pierced by appliances designed for type 200 cartridges. | | P |
| 4 | Types of test | | - |
| 4.1 | Migration tests | | - |
| | "Migration" tests for the determination of overall migration are carried out using the "food simulants" and "conventional migration test conditions", see 5.1, 5.2 and Table 1. | | P |
| 4.2 | Substitute tests | | |
| | If the migration test using fatty food simulants is not feasible, for technical reasons connected with the test method, "substitute tests" which use test media under the conventional substitute test conditions may be appropriate. The substitute tests involve the use of all of the substitute test media, 95 % ethanol in aqueous solution, iso-octane and modified polyphenylene oxide under the test conditions corresponding to the test conditions for simulant D, see Table 4. A new test specimen is used for each test. The reduction factors, 2 to 5, are applicable to these substitute tests, see clause 6. To ascertain compliance with the overall migration limit the highest value obtained using all of the test media is selected. | | P |

| | | | |
|--------------|--|--|---|
| 4.3 | Alternative tests | | - |
| 4.3.1 | "Alternative tests" with volatile media | | |
| | <p>The results of alternative tests, using volatile test media such as iso-octane and 95 % ethanol in aqueous solution or other volatile solvents or mixtures of solvents may be used to demonstrate compliance with the legislative limit, provided that:</p> <p>a) the result obtained in a comparison test shows that the value is equal to or greater than those obtained in the migration test with a fatty food simulant;</p> <p>b) the migration in the alternative test does not exceed the overall migration limit, after application of appropriate reduction factors.</p> <p>If either or both conditions are not fulfilled, then the migration tests (4.1) have to be performed.</p> | | P |
| 4.3.2 | Extraction tests | | |
| | <p>Other tests are permitted which use other test media having very strong extractive power under severe test conditions, if it is generally recognized, on the basis of scientific evidence, that the results obtained using these extraction tests are equal to or higher than those obtained with simulant D.</p> | | P |
| 4.4 | Criteria for the use of substitute tests | | |
| | <p>The use of substitute tests is justified, when the migration test carried out with each of the possible simulants D is found to be inapplicable due to technical reasons connected with the migration test, e.g. interferences, incomplete extraction of oil, absence of stability of the mass of the plastics, excessive absorption of fatty food simulant, reaction of components with the fat.</p> | | P |
| 5 | Food simulants, test media and reagents | | - |
| 5.1 | Aqueous food simulants | | - |
| | <p>The aqueous food simulants shall be of the following quality:</p> <ul style="list-style-type: none"> - distilled water or water of equivalent quality, simulant A; - 3 % acetic acid (w/v) in aqueous solution, simulant B; <p>For the purposes of this standard this means a solution prepared by diluting 30 g of acetic acid with distilled water to a volume of 1 l;</p> <ul style="list-style-type: none"> - 10 % ethanol (v/v) in aqueous solution, simulant C. <p>For liquids or beverages with an ethanol content greater than 10 % (v/v) the test is carried out with aqueous solutions of ethanol of a similar strength.</p> <p>Each of the above food simulants shall give a non-volatile residue of less than 5 mg/l, when evaporated to dryness and dried to constant mass at 105 °C to 110 °C.</p> | | P |
| 5.2 | Fatty food simulants | | - |

| | | | |
|--------------|---|--|---|
| | <p>The fatty food simulants are as follows: - rectified olive oil, "reference simulant D". This "reference simulant D" may be replaced by a synthetic mixture of triglycerides or sunflower oil or corn oil with standardized specifications. These are known as "other fatty food simulants" and called "simulant D". For the characteristics of olive oil, a synthetic mixture of triglycerides, sunflower oil and corn oil, see annex A. NOTE When these fatty food simulants are used to simulate some classes of food, reduction factors can be used, see 6.2 and Table 2.</p> | | P |
| 5.3 | Test media | | - |
| 5.3.1 | Test media for substitute tests | | |
| | <p>The test media to be used in substitute tests are iso-octane, 95 % ethanol in aqueous solution and a modified polyphenylene oxide (MPPO). The characteristics of modified polyphenylene oxide are to be found in annex A.</p> | | P |
| 5.3.2 | Test media for alternative tests | | - |
| | <p>These are volatile media such as iso-octane and 95 % ethanol in aqueous solution or other volatile solvents or mixtures of solvents.</p> | | P |
| 6 | Migration test, substitute test and alternative test conditions | | - |
| 6.1 | Test conditions for migration tests | | |
| | <p>NOTE 1 The basic rules necessary for testing the overall migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs are laid down (reference Council Directive 82/711/EEC and its subsequent amendments, [3], [4] and [5]). NOTE 2 The test times and temperatures are chosen according to conditions of contact in actual use. Tolerances on contact times and contact temperatures applicable to all Parts of this standard are detailed in Tables B.1 and B.2.</p> | | P |
| 6.1.1 | General | | - |

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| | <p>The migration tests are to be carried out, selecting from the times and temperatures specified in Table 3 those which correspond to the worst foreseeable conditions of contact for the plastics material or article and to any labelling information on maximum temperature for use. Therefore, if the final plastics material or article is intended for a food contact application covered by a combination of two or more times and temperatures taken from the table, the migration test shall be carried out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.</p> <p>In some instances, it may be necessary to measure the temperature of plastics materials and articles at the food/plastic interface during microwave and conventional oven heating.</p> <p>NOTE A method for the determination of temperature of plastics materials and articles at the plastics/food interface is being prepared by a Subcommittee (SC1) of CEN/TC 194 'Utensils in contact with food' under work item 00194078.</p> | | P |
| 6.1.2 | Contact conditions generally recognized as more | | - |
| | <p>NOTE In the application of the general criteria that the determination of the migration should be restricted to the test conditions which, in the specific case under examination, are recognized to be the most severe on the basis of scientific evidence, some specific examples for the test conditions are given below.</p> | | P |
| 6.1.2.1 | Contact with foodstuffs at any condition of time and temperature | | - |
| | <p>Many articles may be used at a variety of temperatures and for varying times, or their conditions of use may not be known. Where the plastics material or article may in actual use be employed under any conditions of contact time, and no labelling or instructions are given to indicate contact temperature and time expected in actual use, depending on food type(s), simulants(s) A and/or B and/or C shall be used for 4 h at 100 °C or for 4 h at reflux temperature and/or simulant D shall be used only for 2 h at 175 °C.</p> | | P |
| 6.1.2.2 | Contact with foodstuffs at room temperature or below for an unspecified period | | - |
| | <p>Where the materials and articles are labelled for use at room temperature or below or where the materials and articles by their nature are clearly intended for use at 40 °C for 10 days. These conditions of time and temperature are conventionally considered to be the more severe.</p> | | P |
| 6.1.3 | Contact for less than 15 min at temperatures between 70 °C and 100 °C | | - |

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| | If the plastics material or article may in actual use be employed for periods of less than 15 min at temperatures between 70 °C and 100 °C, e.g. hot fill, and is so indicated by appropriate labelling or instructions, only the 2 h test at 70 °C shall be carried out. However if the material or article is intended to be used also for storage at room temperature, the test at 70 °C for 2 h is replaced by a test at 40 °C for 10 d, this being conventionally the more severe test. | | P |
| 6.1.4 | Contact in a microwave oven | | - |
| | For materials and articles intended for use in microwave ovens, migration testing may be carried out in either a conventional oven or a microwave oven provided the appropriate time and temperature conditions are selected. | | P |
| 6.1.5 | Contact conditions causing changes in physical or other properties | | - |
| | If it is found that carrying out the test under the chosen contact conditions causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place. | | P |
| 6.1.6 | Contact not covered by the conventional condition for migration tests | | - |
| | In those instances where the conventional conditions for migration tests do not adequately cover the conditions in actual use, for instance contact at temperatures greater than 175 °C or contact times of less than 5 min, other contact conditions may be used which are more appropriate to the case under examination, provided that the selected conditions represent the worst foreseeable conditions of contact. | | P |
| 6.1.7 | Testing at low temperatures | | - |
| | Testing with fats at 5 °C may lead to technical problems if the fat partially solidifies or, in the case of the synthetic triglyceride mixture, totally solidifies. A sunflower oil, which is free of components which solidify at the temperature of test (i.e. a "dewaxed" oil), may be used. However, with olive oil and sunflower oil the test is usually without this problem at 10 °C. If the overall migration does not exceed the limit when tested at 10 °C this indicates that it would not have exceeded the limit at 5 °C. Testing by total immersion or in a cell or in a pouch is practicable at low temperatures, although if a cell or pouch is used for the fatty food simulant where a visual check on solidification is difficult, a dewaxed simulant shall be used. The method of test for the determination of overall migration at low temperatures (5 °C and 20 °C) is given in EN 1186-12. | | P |
| 6.1.8 | Testing at high temperature | | - |

| | | | |
|---------------|---|--|---|
| | In practice, severe difficulties have been found in obtaining consistent and comparable results in interlaboratory trials with the test conditions for simulating exposure at temperatures of use in excess of 121 °C. The main source of inconsistency appears to be due to variation in the time required to achieve the test temperature with olive oil and other fatty food simulants. Various options such as exposure of sample tubes in electrically heated cells, etc. are under investigation as possible solutions to the problem. These have been incorporated into methods described in Part 13 of this standard. | | P |
| 6.1.9 | Caps, gaskets, stoppers or similar sealing devices | | - |
| | In many cases lids and closures may be expected to come into contact with foodstuffs and are tested under similar conditions to the rest of the container. However in some high temperature applications the lid may only be exposed to water vapour and this condensed vapour may be returned to the bulk of the foodstuff. In such cases the lids and closures should be tested with simulant A at reflux. | | P |
| 6.1.10 | Tubing, taps, valves, filters | | |
| | Defining the time of exposure may be difficult for articles such as tubing, taps, valves, filters etc. as they may be in contact with flowing foodstuff. However, this exposure may be considered to be repeated brief contact for the purposes of migration testing. Such articles may be tested by repeated total immersion or by repeated filling. Tubing may be stoppered with an inert stopper. To select the exposure time for tubing, the retention time of the foodstuff, which is subject to the flow rate of the foodstuff, as well as length and diameter of the tubing, shall be taken into account. | | P |
| 6.2 | Test conditions for substitute tests | | |
| | Corresponding conventional conditions for the substitute tests have been agreed for examples of the most important conventional migration test conditions, see Table 4. | | P |
| 6.3 | Test conditions for alternative tests | | |
| 6.3.1 | Alternative test with volatile media | | - |
| | The test conditions for alternative tests using volatile test media such as iso-octane and 95 % ethanol in aqueous solution or other volatile solvents or mixtures of solvents are chosen so that: a) the result obtained in a comparison test shows that the value is equal to or greater than those obtained in the migration test with a fatty food simulant; b) the migration in the alternative test does not exceed the migration limits, after application of appropriate reduction factors, see clause 6. If either or both conditions are not fulfilled, then the migration tests with fatty food simulants have to be performed. | | |
| 6.3.2 | Extraction tests | | - |
| | The test conditions are selected so that the results obtained using these extraction tests are equal to or higher than those obtained with simulant D. | | P |

Table 3 — Conventional conditions for migration tests with food simulant

| Conditions of contact in worst foreseeable use | Test conditions |
|---|------------------------------|
| Contact time | Test time |
| $t \leq 5 \text{ min}$ | see the conditions in 7.1.6 |
| $5 \text{ min} < t \leq 0,5 \text{ h}$ | 0,5 h |
| $0,5 \text{ h} < t \leq 1 \text{ h}$ | 1 h |
| $1 \text{ h} < t \leq 2 \text{ h}$ | 2 h |
| $2 \text{ h} < t \leq 4 \text{ h}$ | 4 h |
| $4 \text{ h} < t \leq 24 \text{ h}$ | 24 h |
| $t > 24 \text{ h}$ | 10 d |
| Contact temperature | Test temperature |
| $T \leq 5 \text{ °C}$ | 5 °C |
| $5 \text{ °C} < T \leq 20 \text{ °C}$ | 20 °C |
| $20 \text{ °C} < T \leq 40 \text{ °C}$ | 40 °C |
| $40 \text{ °C} < T \leq 70 \text{ °C}$ | 70 °C |
| $70 \text{ °C} < T \leq 100 \text{ °C}$ | 100 °C or reflux temperature |
| $100 \text{ °C} < T \leq 121 \text{ °C}$ | 121 °C (*) |
| $121 \text{ °C} < T \leq 130 \text{ °C}$ | 130 °C (*) |
| $130 \text{ °C} < T \leq 150 \text{ °C}$ | 150 °C (*) |
| $T > 150 \text{ °C}$ | 175 °C (*) |
| (*) This temperature shall be used only for simulant D. For simulants A, B, or C the test may be replaced by a test at 100 °C or at reflux temperature for a duration of four times the time selected according to the general rules of 7.1.1 | |

NOTE These conventional conditions for migration tests with food simulants are specified in Council Directive 82/711/EEC [3] as amended by [4] and [5].

7.1.2.2 Contact with foodstuffs at room temperature or below for an unspecified period

Where the materials and articles are labelled for use at room temperature or below or where the materials and articles by their nature are clearly intended for use at room temperature and below, the test shall be carried out at

Table 4 — Conventional conditions for substitute tests

| Test conditions with simulant D | Test conditions with iso-octane | Test conditions with ethanol 95 % | Test conditions with MPPO(*) |
|--|---------------------------------|-----------------------------------|------------------------------|
| 10 d at 5 °C | 0,5 d at 5 °C | 10 d at 5 °C | - |
| 10 d at 20 °C | 1 d at 20 °C | 10 d at 20 °C | - |
| 10 d at 40 °C | 2 d at 20 °C | 10 d at 40 °C | - |
| 2 h at 70 °C | 0,5 h at 40 °C | 2 h at 60 °C | - |
| 0,5 h at 100 °C | 0,5 h at 60 °C (**) | 2,5 h at 60 °C | 0,5 h at 100 °C |
| 1 h at 100 °C | 1,0 h at 60 °C(**) | 3,0 h at 60 °C(**) | 1 h at 100°C |
| 2 h at 100°C | 1,5 h at 60 °C(**) | 3,5 h at 60 °C(**) | 2 h at 100 °C |
| 0,5 h at 121 °C | 1,5 h at 60 °C(**) | 3,5 h at 60 °C(**) | 0,5 h at 121 °C |
| 1 h at 121 °C | 2,0 h at 60 °C(**) | 4,0 h at 60 °C(**) | 1 h at 121 °C |
| 2 h at 121 °C | 2,5 h at 60 °C(**) | 4,5 h at 60 °C(**) | 2 h at 121 °C |
| 0,5 h at 130 °C | 2,0 h at 60 °C(**) | 4,0 h at 60 °C(**) | 0,5 h at 130 °C |
| 1 h at 130 °C | 2,5 h at 60 °C(**) | 4,5 h at 60 °C(**) | 1 h at 130 °C |
| 2 h at 150 °C | 3,0 h at 60 °C(**) | 5,0 h at 60 °C(**) | 2 h at 150 °C |
| 2 h at 175 °C | 4,0 h at 60 °C(**) | 6,0 h at 60 °C (**) | 2 h at 175 °C |
| (*) MPPO = modified polyphenylene oxide | | | |
| (**) The volatile test media are used up to a maximum temperature of 60 °C. A precondition of using the substitute tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse the test specimen in olive oil under the appropriate conditions. If the physical properties are changed (e.g. melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed then proceed with the substitute tests using new specimens. | | | |

NOTE 1 These conventional conditions for substitute tests are specified in Commission Directive 97/48/EC [5] the second amendment to Council Directive 82/711/EEC [3].

NOTE 2 Since conducting a 12 h test can pose organizational problems to a laboratory, a prolonged test, for example of a more manageable 16 h, can be applied. This is acceptable as long as the overall migration limit is not exceeded under such more severe test conditions."

Other test conditions may be used. In this case the examples detailed above shall be taken into account as well as existing experience for the type of polymer under examination.

Annex A (normative)

Characteristics of fatty food simulants and test media

A.1 Characteristics of rectified olive oil, reference simulant D

| | |
|--|--------------------|
| iodine value (Wijs) | = 80 to 88 |
| refractive index at 25 °C | = 1,4665 to 1,4679 |
| acidity, expressed as % oleic acid | = 0,5 % maximum |
| peroxide number, expressed as oxygen milliequivalent per kg of oil | = 10 maximum |
| unsaponifiable matter | = < 1 % |

A.2 Composition of the mixture of synthetic triglycerides, simulant D

Table A.1 — Fatty acid distribution

| Number of C-atoms in fatty acid moiety | 6 | 8 | 10 | 12 | 14 | 16 | 18 | Others |
|--|----|--------|---------|----------|----------|---------|---------|--------|
| GLC area % | -1 | 6 to 9 | 8 to 11 | 45 to 52 | 12 to 15 | 8 to 10 | 8 to 12 | ≤ 1 |

Purity

| | |
|---|--------------|
| content of monoglycerides (enzymatically) | ≤ 0,2 % |
| content of diglycerides (enzymatically) | ≤ 2,0 % |
| unsaponifiable matter | ≤ 0,2 % |
| iodine value (Wijs) | ≤ 0,1 % |
| acid value | ≤ 0,1 % |
| water content (K. Fischer) | ≤ 0,1 % |
| melting point | 28 °C ± 2 °C |

Typical absorption spectrum (thickness of layer d=1cm, reference: water, 35 °C)

| | | | | | | | | | |
|-------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| wavelength (nm) | 290 | 310 | 330 | 350 | 370 | 390 | 430 | 470 | 510 |
| transmittance (%) | ~2 | ~15 | ~37 | ~64 | ~80 | ~88 | ~95 | ~97 | ~98 |

at least 10 % light transmittance at 310 nm (cell of 1 cm, reference: water, 35 °C)

A.3 Characteristics of sunflower oil, simulant D

| | |
|----------------------------------|-----------------|
| iodine value (Wijs) | =120 to 145 |
| refractive index at 20 °C | =1,474 to 1,476 |
| saponification number | =188 to 193 |
| relative density at 20 °C | =0,918 to 0,925 |
| unsaponifiable matter | = < 0,5 % |
| acidity, expressed as oleic acid | =< 0.5% |

A.4 Characteristics of corn oil, simulant D

| | |
|----------------------------------|------------------|
| iodine value (Wijs) | =110 to 135 |
| refractive index at 20 °C | = 1.471 to 1.473 |
| acidity, expressed as oleic acid | = <0.5% |
| peroxide number | = <10 |
| unsaponifiable matter | = < 0.5% |

A.5 Characteristics of modified polyphenylene oxide (MPPO)

| | |
|------------------|--------------------|
| molecular weight | 500,000 to 100,000 |
| size | 60 mesh to 80 mesh |
| T_{max} | 350 °C |
| specific mass | 0,23 g/ml |

Annex B (normative)

Tolerances on contact times and contact temperatures applicable to all Parts of this standard

Tolerances on contact times and contact temperatures applicable to all Parts of this standard

Table B.1 - Contact times and tolerances

| Contact times and tolerances |
|------------------------------|
| +1 30 0 min |
| +1 60 0 min |
| +3 90 0 min |
| +5 120 0 min |
| +5 150 0 min |
| +7 180 0 min |
| +8 210 0 min |
| +9 240 0 min |
| +10 270 0 min |
| +12 300 0 min |
| +15 360 0 min |
| +0,5 24 0 h |
| +0,5 48 0 h |
| +5 240 0 h |

Table B.2 - Contact temperatures and tolerances

| Contact temperatures and tolerances |
|-------------------------------------|
| 5 °C ± 1 °C |
| 20 °C ± 1 °C |
| 30 °C ± 1 °C |
| 40 °C ± 1 °C |
| 50 °C ± 2 °C |
| 60 °C ± 2 °C |
| 70 °C ± 2 °C |
| 80 °C ± 3 °C |
| 90 °C ± 3 °C |
| 100 °C ± 3 °C |
| 121 °C ± 3 °C |
| 130 °C ± 5 °C |
| 140 °C ± 5 °C |
| 150 °C ± 5 °C |
| 160 °C ± 5 °C |
| 170 °C ± 5 °C |
| 175 °C ± 5 °C |

Annex C
(informative)

Supports and cells

Dimensions in millimetres

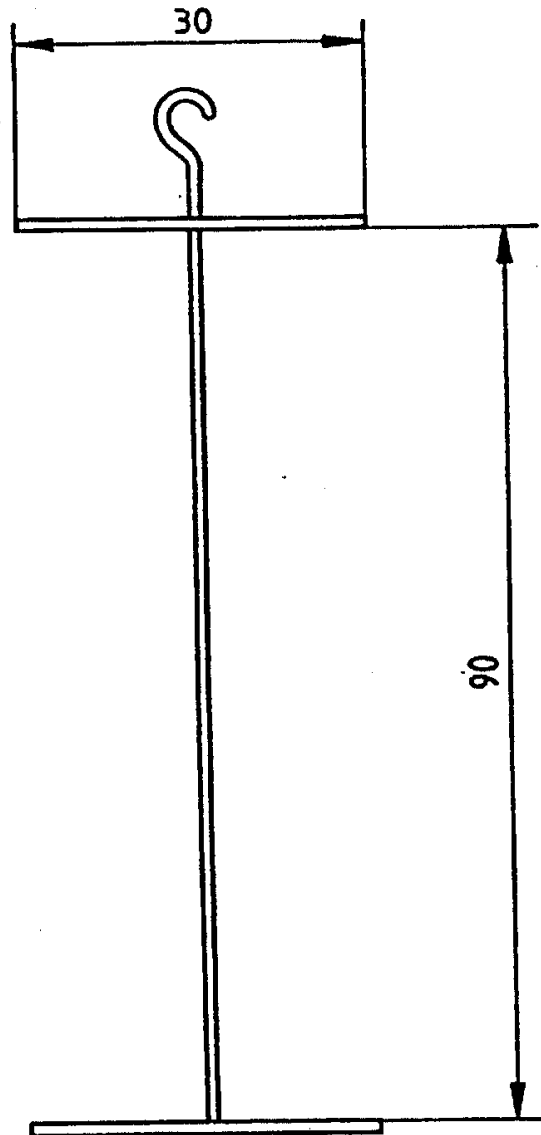


Figure C.1 — Example of support

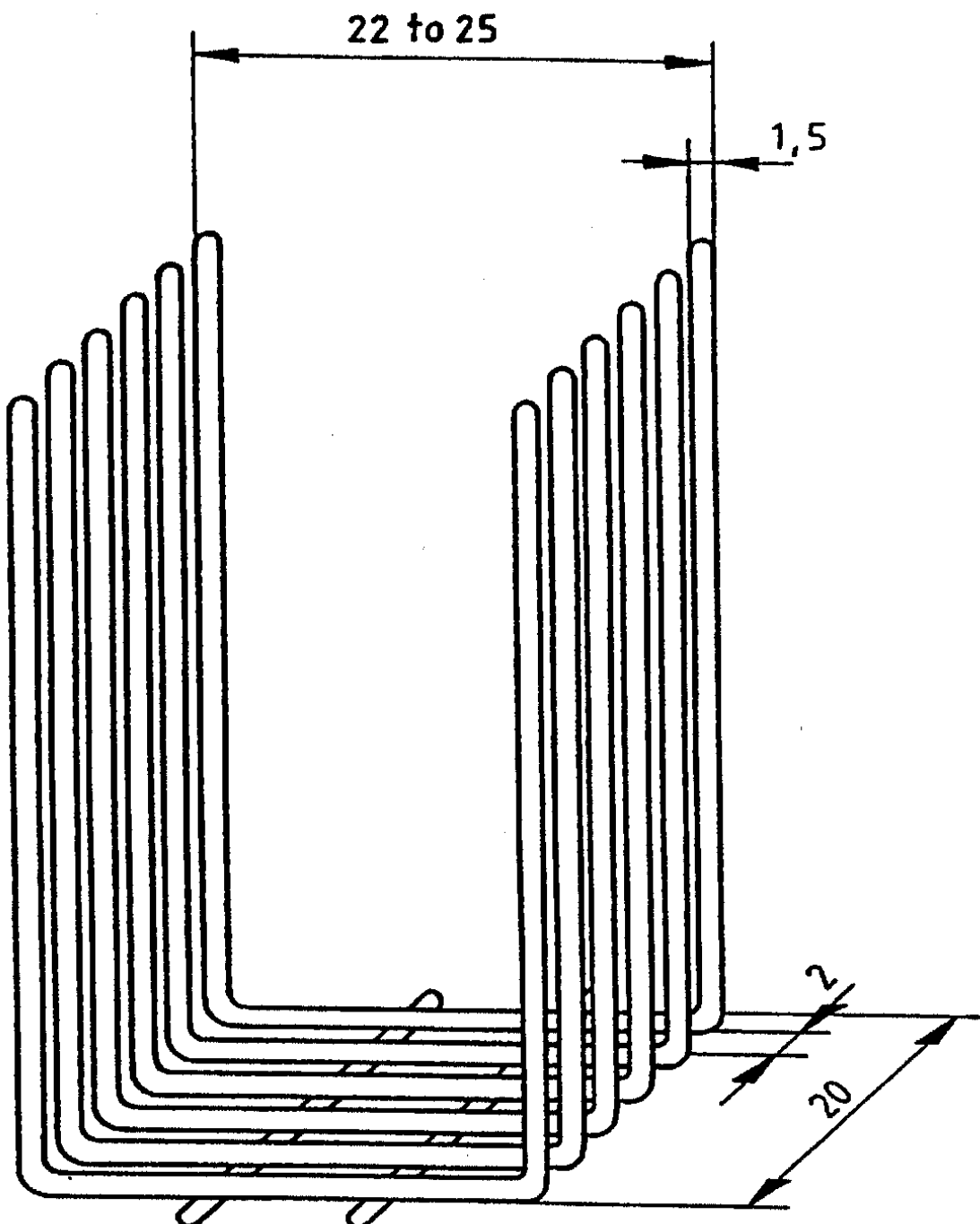
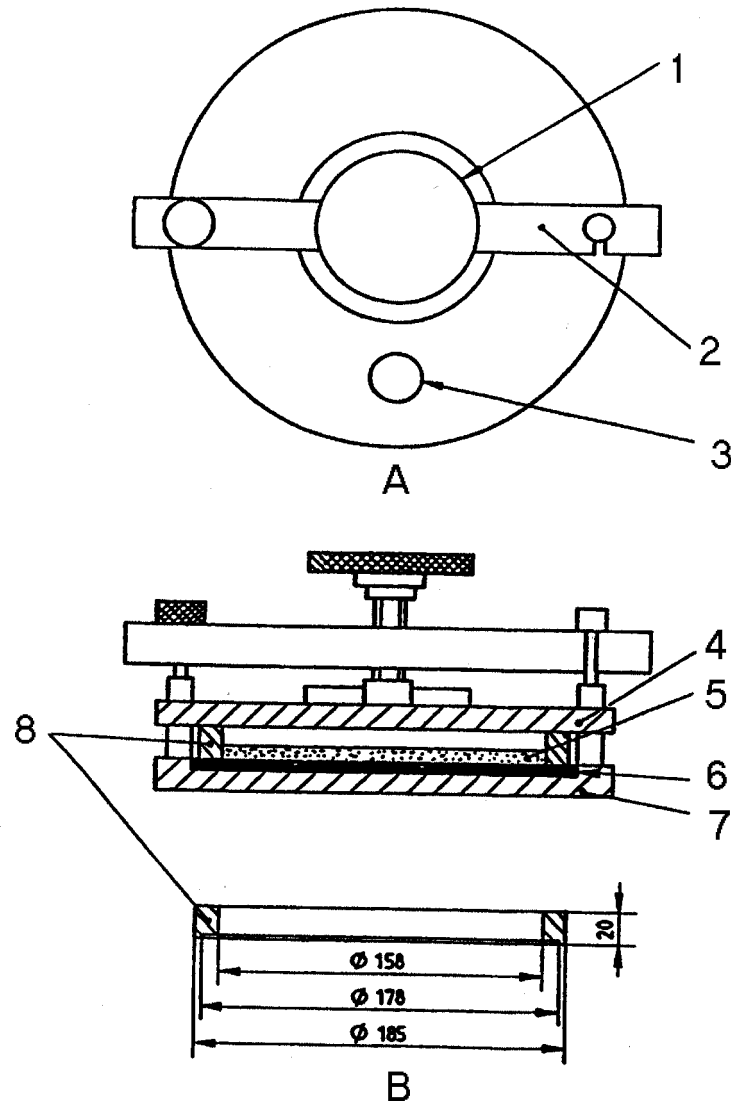


Figure C.2 — Example of support

Dimensions in millimetres

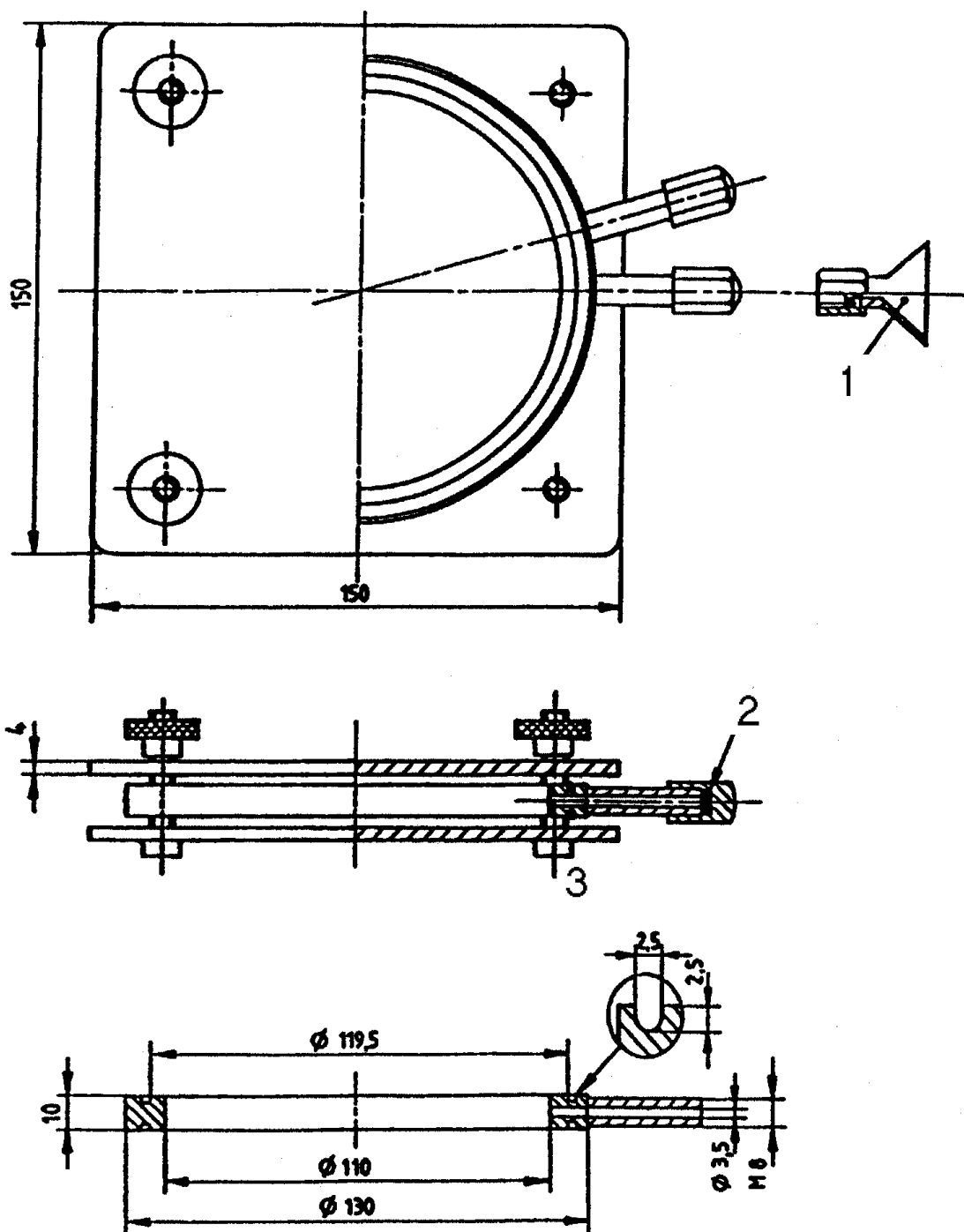


Key

- A Plan elevation
- 1 Clamp screw
- 2 Clamp bar
- 3 Filler plug
- B Side elevation
- 4 Lid
- 5 Food simulant
- 6 Rubber mat
- 7 Base plate
- 8 Sealing ring

Figure C.3 — Cell type A

Dimensions in millimetres

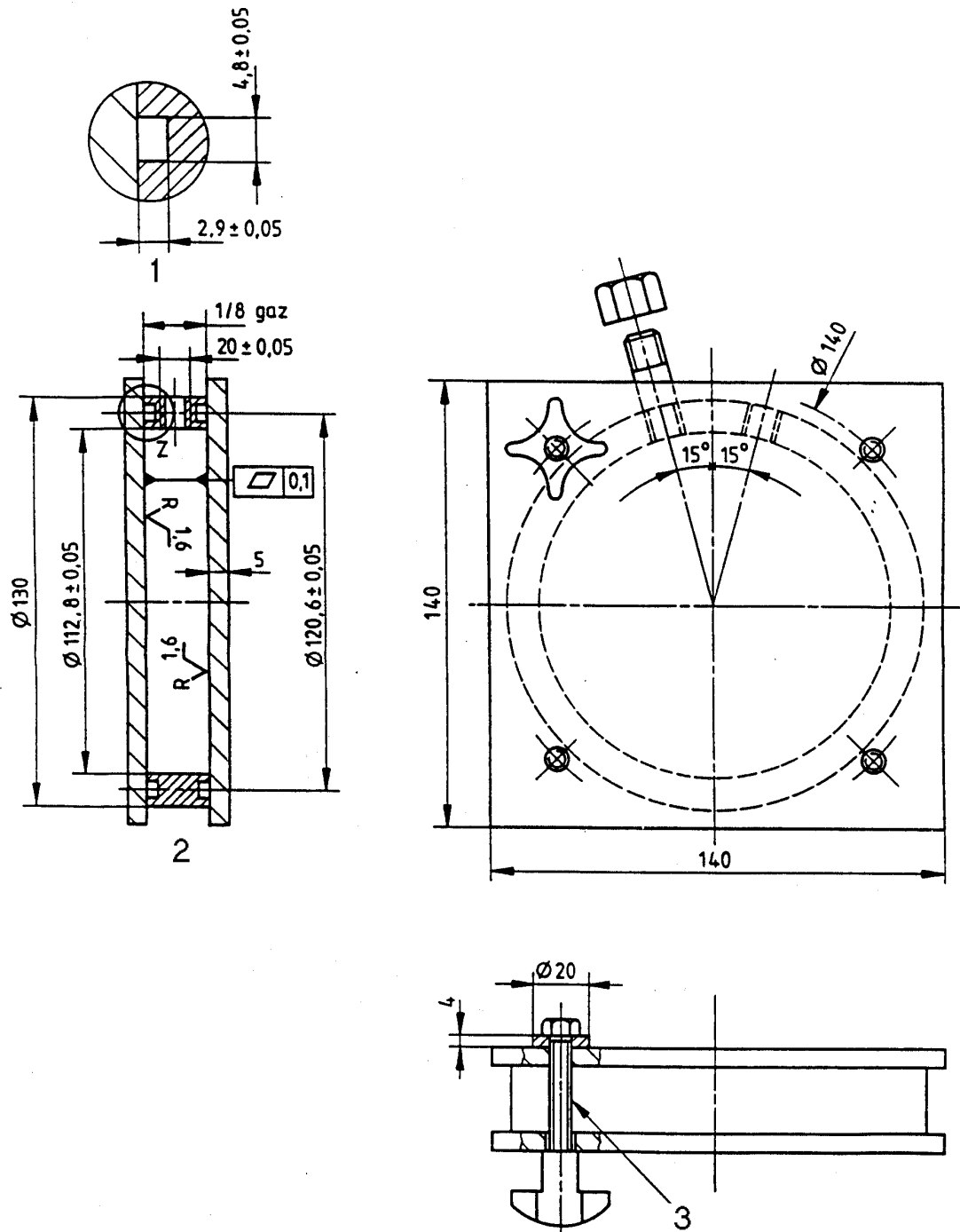


Key

- 1 Funnel for filling
- 2 PTFE disk
- 3 PTFE 'O' – ring (119,5 × Ø 3)

Figure C.4 — Cell type B

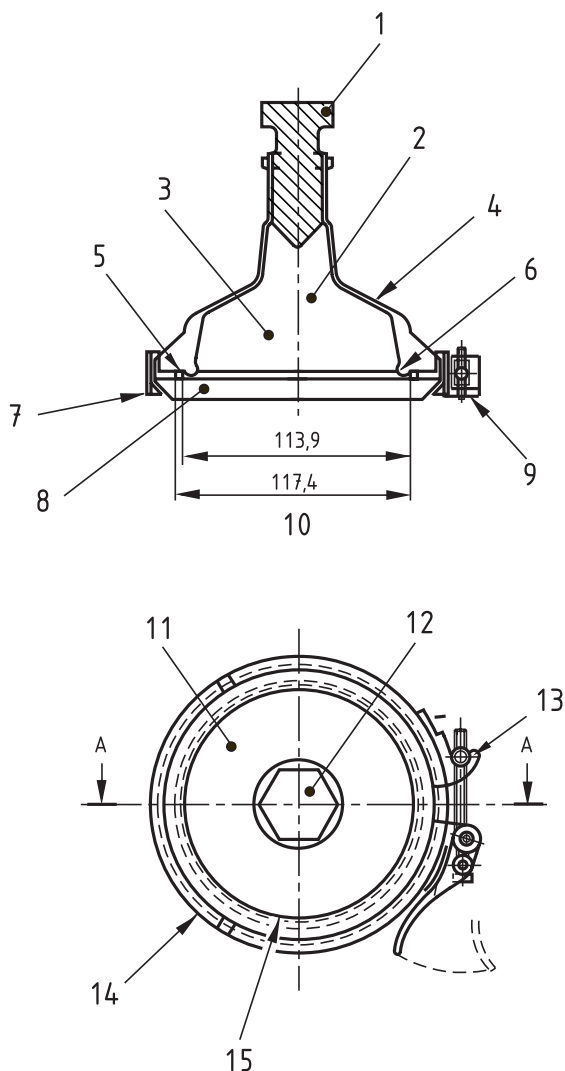
Dimensions in millimetres



Key

- 1 Detail Z
- 2 'O' – ring $\varnothing 117,07 / 124,13 / 3,53$
- 3 Screw HM8-50

Figure C.5 — Cell type C



Key

- 1 Glass stopper
- 2 Total inner volume : 296 ml (maximum volume of simulant : 250 ml)
- 3 Exposed surface area of circular test specimens : $1,019 \text{ dm}^2$
- 4 Glass bell
- 5 Sealing ring ('O' ring) (silicon rubber sheathed in PTFE)
- 6 Raised edge to fix the 'O' ring in place
- 7 Tension ring (stainless steel)
- 8 PTFE plate
- 9 Tensioning seal (stainless steel)
- 10 Sectional view A-A
- 11 Glass bell
- 12 Glass stopper
- 13 Tensioning seal (stainless steel)
- 14 Tension ring (stainless steel)
- 15 Sealing ring

Figure C.6 — Cell type D

Dimensions in millimetres

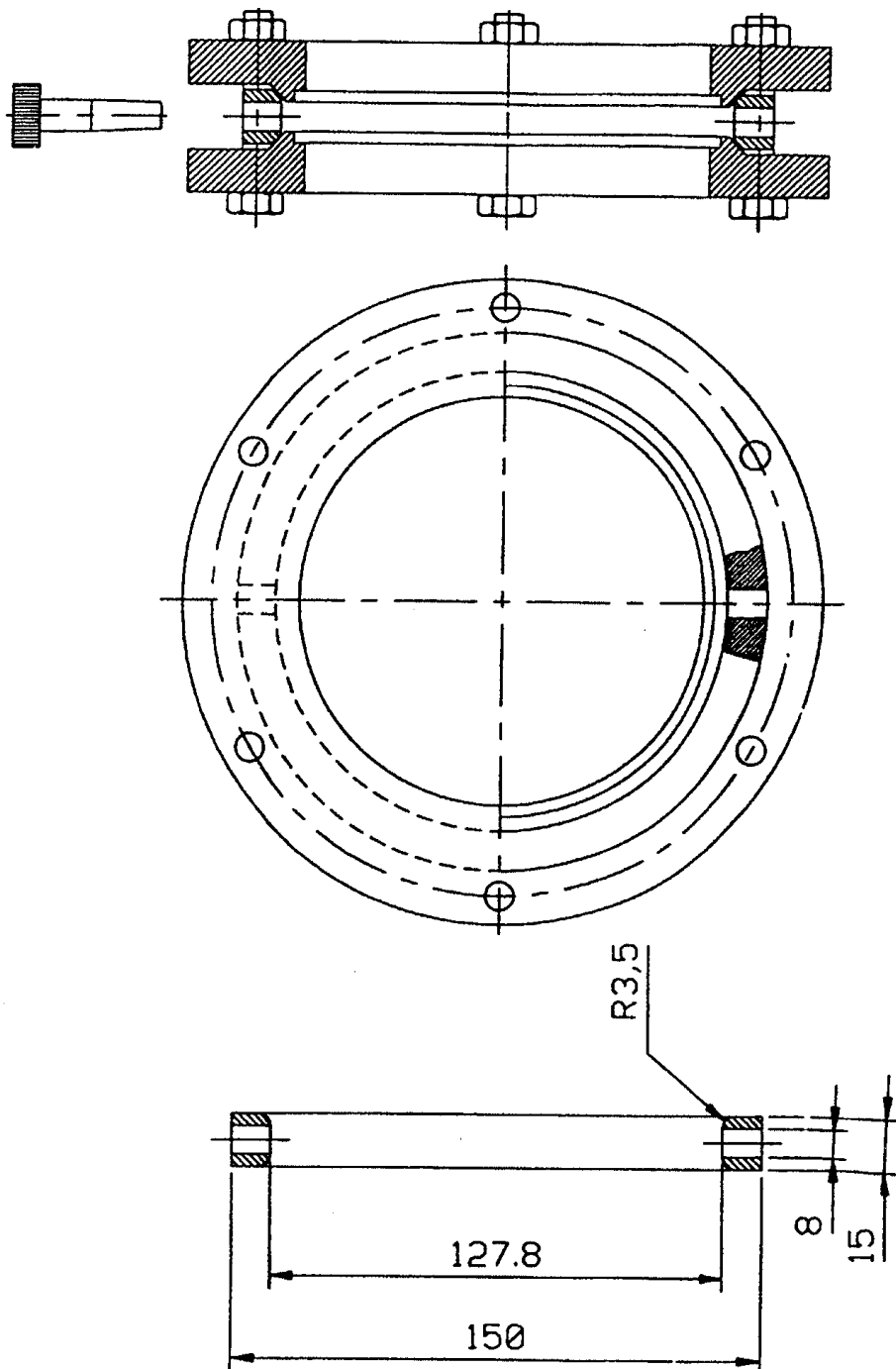
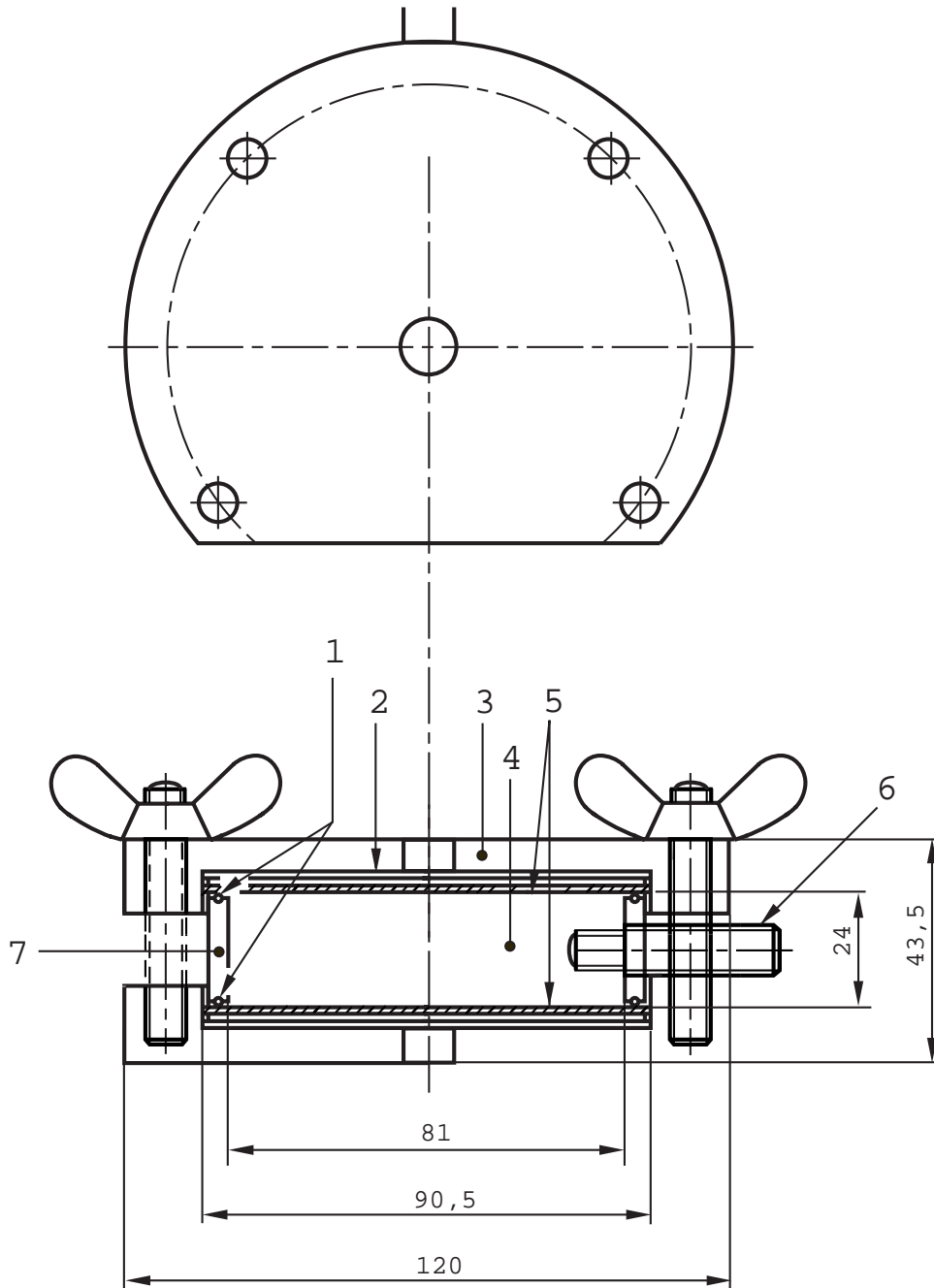


Figure C.7 — Cell type E

**Key**

- 1 Sealing ring
- 2 Lid (stainless steel)
- 3 Body (aluminium)
- 4 (simulant)
- 5 Test sample
- 6 Stopper (PTFE)
- 7 Ring (stainless steel)

Figure C.8 — Cell type F

Annex ZA (informative)

Relationship of this European Standard with Council Directive 89/109/EEC and Commission Directive 90/128/EEC and associated Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association (EFTA).

NOTE Other requirements and other EU Directives may be applicable to products falling within the scope of this standard.

The clauses of this standard are likely to support, Directives 89/109/EEC [1], 90/128/EEC [2], 82/711/EEC [3] and its amendments 93/8/EEC [4] and 97/48/EC [5], and 85/572/EEC [6].

Compliance with this standard provides one means of conforming to the overall migration requirements of the Directive concerned and associated EFTA regulations.

European Commission Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs, [2] specifies in article 2.

Plastics materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of materials or articles (overall migration limit). However this limit shall be 60 milligrams of constituents released per kilogram of foodstuff in the following cases :

- a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 l;
- b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
- c) caps, gaskets, stoppers or similar devices for sealing.

European Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs [3], and the subsequent amendments Directives 93/8/EEC [4] and 97/48/EC [5], recognizes that there are difficulties in the determination of the migration in food products and allows use of food simulants with conventional test conditions, which reproduce, as far as possible, the migration phenomena which may occur with contact between the article and foodstuffs. There are four food simulants:

- simulant A, distilled water or water of equivalent quality;
- simulant B, 3% acetic acid (w/v) in aqueous solution;
- simulant C, 10% ethanol (v/v) in aqueous solution;
- simulant D, rectified olive oil, or other fatty food simulants.

European Directive 82/711/EEC and the subsequent amendments also contain the conventional test conditions (time and temperature) for migration tests with food simulants. European Commission Directive 97/48/EC, the second amendment to European Council Directive 82/711/EEC, also contains test media and conventional test conditions for 'substitute tests'. Substitute tests may be performed in place of migration tests with simulant D, if it has been shown that for technical reasons connected with the method of analysis it is not feasible to obtain a valid test result in a migration test with simulant D.

European Council Directive 85/572/EEC laying down the list of simulants to be used for testing of constituents of plastics materials and articles intended to come into contact with foodstuffs [6] has a table in the Annex which

Sample of photo



Sample of photo



Sample of photo



*** End of Report ***

DECLARE OF CONFORMITY

With EU Directive of GPSD Directive 2001/95/EC

Holder: Qingdao Tide Sports Products Co.,Ltd.
Address: 115# Xianggongshan Road, Binhai Street, Huangdao Zone, Qingdao City, China.
Product: Mouthguards
Model(s): EVA QTMG001-QTMG100,Silicone QTSG001-QTSG100,TPR QTTG001-QTTG100
Standards: EN1186-1:2002; EN 957-1:2005

Based upon the voluntary assessment of the product sample and Technical Construction File, the apparatus is deemed to meet the requirements of the above standards and EC directives.

The manufacturer has the responsibility for ensuring that all serial manufacture of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.



Date: 16/3/2022

Stamp: _____

青岛伟人体育用品有限公司
QINGDAO TIDE SPORTS PRODUCTS CO., LTD.

张宏鉴

GENERAL MANAGER

The CE marking may be used if all relevant and effective EC directives are complied with.

contains a non-exhaustive list of foodstuffs and which identify the simulants to be used in migration tests on those plastic materials and articles intended to come into contact with a particular foodstuff or group of foodstuffs.

This standard contains information on the selection of test methods for the measurement of overall migration from plastics materials to food simulants, or test media, using conventional contact test conditions of time and temperature, to determine compliance with the legislative overall migration limit specified in article 2 of European Commission Directive 90/128/EEC.

These test methods may also be used for the verification of compliance with the specific migration limits provided for in paragraph 1 of Commission Directive 90/128/EEC, if it can be established that compliance with the overall migration limit laid down in Article 2 of Commission Directive 90/128/EEC implies that the specific migration limits are not exceeded. It should be borne in mind that the test methods for overall migration described in this standard, in general, measure the migration of non volatile substances.

Commission Directive 90/128/EEC also specifies that the migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases where there is conclusive proof that the specified analytical method is inadequate from the technical standpoint.

In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Annex II of Commission Directive 90/128/EEC, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However, Commission Directive 90/128/EEC requires that the sum of all specific migrations determined shall not exceed the overall migration limit.

Bibliography

- [1] Commission of the European Communities, Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuff (89/109/EEC), Official Journal of the European Communities, 11 February 1989, no. L 40, p 38.
- [2] Commission of the European Communities, Commission Directive of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs (90/128/EEC), Official Journal of the European Communities, 13 December 1990, no. L349, p26. Corrigendum of the previous publication, Official Journal of the European Communities, 21 March 1990, no.L 75. p19.
- [3] Commission of the European Communities, Council Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (82/711/EEC), Official Journal of the European Communities, 23 October 1982, no. L 297, p 26.
- [4] Commission of the European Communities, Commission Directive of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (93/8/EEC), Official Journal of the European Communities, 14 April 1993, no. L 90, p 22.
- [5] Commission of the European Communities, Commission Directive 97/48/EC of 29 July 1997 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs , Official Journal of the European Communities, 12 August 1997, no. L 222, p 10
- [6] Commission of the European Communities, Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastics materials and articles intended to come into contact with foodstuffs (85/572/EEC), Official Journal of the European Communities, 31 December 1985, no. L372, p14.

Notice

- 1. This test report shall be invalidation without the cachet of the testing laboratory.**
- 2. This copied report shall be invalidation without sealed the cachet of the testing laboratory.**
- 3. This report shall be invalidation without tester signature.**
- 4. This altered report shall be invalidation.**
- 5. Client shall put forward demurrer within 15 days after received report.**
The testing laboratory shall refuse disposal if exceeded the time limit.
- 6. The test results presented in this report relate only to the object tested.**