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Regulations Relating to the Quality Seal for Condoms

Lucerne, 11 May 2011

Contents

The requirements at a glance

- Producers, packing agents or importers may use the Quality Seal for Condoms if they agree by contract to fulfil all parts of the Regulations relating to the Quality Seal for Condoms.
- Condoms must conform to the Swiss Ordinance on Medical Devices (MepV)
- Each batch must be tested by an independent laboratory before released for sale (lot-by-lot testing). A burst test and a freedom from holes test must be carried out.
- The arithmetical mean of the bursting volume of the random sample tested must be at least 28 litres. A batch is passed if, for an AQL of 1.0, the burst volume of the individual test is at least 75% of the arithmetic mean of the bursting volume of the batch and if the bursting pressure for the individual test is over 1.0 kPa.
- The requirements of EN ISO 4074 apply to the test on freedom from holes for natural rubber latex condoms.

- Procedure:
  A random sample will normally be taken from a completed batch by an agent of the Verein Gütesiegel für Präservative (Quality Seal for Condoms Association) and tested at an accredited laboratory, the accreditation of which must be recognised by the EA, the European Co-operation for Accreditation. In a separate contract relating to the use of the Quality Seal, the User of the Quality Seal undertakes to sell only tested batches on the Swiss market.
- The Association ensures that the Regulations are observed by taking market samples. Analysis of the test results is carried out in accordance with the Appendix of 30 March 2004.

All details are covered by the following Regulations Relating to the Quality Seal for Condoms. If any doubt should arise, the wording used in the German version of the Regulations applies.

1 Purpose of the Quality Seal

- Apart from abstinence and being in a mutually faithful HIV-free relationship, condoms have proven to be the only effective prophylactic measure which can prevent the sexual transmission of HIV. If they are to fulfil this protective function, condoms must be used correctly and must not tear when being used.
- The Quality Seal denotes condoms which are of a high standard of quality and which meet the requirements of the Swiss Ordinance on Medical Devices (MepV), also with regard to packaging and labelling.
- Condoms with the Quality Seal usually are made of natural rubber latex. Condoms made from other materials may also be granted the Quality Seal. In this case special requirements have to be stipulated.
- The Quality Seal for Condoms helps consumers to choose a good or very good quality product from amongst those on the market. The Quality Seal for Condoms guarantees that the highest quality requirements have been tested and confirmed for each batch before it is released for sale.

2 Scope

The Quality Seal applies to condoms sold in Switzerland. The sale of condoms so designated is allowed in other countries.

3 Definitions

3.1 Batch, individual container, consumer package, width
See the current version of the standard EN ISO 4074.

3.2 Awarding Body for the Quality Seal
The Awarding Body is the Verein «Gütesiegel für Präservative» (Association for the Quality Seal for Condoms) (for registered office see Section 13).

3.3. Users of the Quality Seal
Producers, packing agents and importers of condoms are eligible to become Users of the Quality Seal, and to these the Awarding Body grants the right to use the Quality Seal within the terms of reference of the Regulations.

3.4 Continuing production for the Swiss market
Continuing production for the Swiss market means that the manufacturer has specifically selected the relevant batches for the Swiss market.

4 Requirements

The prerequisite for the granting of the Quality Seal is compliance with the MepV. The Verein Gütesiegel für Präservative (Association for the Quality Seal for Condoms) assumes that those condoms, which bear the CE nnnn mark or the MD nnnnn mark comply with the MepV. This includes specific Swiss requirements relating to CE-labelling, such as, among other things, product documentation in three languages and the details of the Swiss agent marketing the product.

If labelling with the Quality Seal is to be justified, every batch must undergo a bursting test and a test for freedom from holes before it is released for sale.

4.1 Bursting test: Requirements relating to bursting pressure and bursting volume
Condoms supplied in individual containers are tested in accordance with EN ISO 4074. The arithmetic mean of the burst volume of the random sample tested must be at least 28 litres. A batch is deemed to be “non conforming” if the number of condoms whose burst pressure is below 1.0 kPa and/or whose burst volume is below 75% of the average for the random sample does not meet the following conditions for the AQL:
In the case of continuing production for the Swiss market (or for the Quality Seal) the random sample must satisfy an AQL of 1.0 in accordance with ISO 2859-1:1999. The sample size will be established in accordance with general inspection level I as per ISO 2859-1: 1999, usually double sampling plan for normal inspection. The User of the Quality Seal is at liberty, however, to demand a single or multiple sampling plan for testing from the testing laboratory.

4.2 Requirements for freedom from holes
In the case of ongoing production for the Swiss market (or the Quality Seal) EN ISO 4074 (AQL 0.25) applies.

4.3 Lot-by-lot testing, forwarding of results of tests
In the case of ongoing production for the Swiss market (or for the Quality Seal) every batch must undergo a burst test and a test to ensure that there are no holes. The results of these tests are to be sent to the Association before release for sale by the testing laboratory. This also applies to tests which have resulted in the rejection of a batch.

5 Sampling

From each batch of condoms which is to bear the Quality Seal, the necessary number of condoms will be taken, after they have been packed, by the Awarding Body or by an appointed agent, in accordance with the sampling plan and will be sent to the testing laboratory. Normally, condoms in individual containers will be selected, before they are packed in consumer packages.

6 Testing

6.1 Batches that are designated to be sold fully or at least partially to the final user

For standard testing purposes the sampling range and the numbers to be accepted and rejected are taken from ISO 2859-1, table 3-A, letter L (bursting test) or letter M (testing for holes) for batches of 35 001 up to 150 000: in the case of AQL 0.25 (testing for holes) acceptance will take place in the case of 0 or a maximum of 3 defective condoms from a sample of 200 or 400 and rejection in the case of 3 or 4 or more defective condoms, in the case of AQL 1.0 (bursting test) acceptance will take place in the case of a maximum of 2 or a maximum of 6 defective condoms from a sample of 125 or 250 and rejection in the case of at least 5 or 7 defective condoms

In accordance with ISO 2859-1, table 3-A, letters L and M for batches of 35 001 up to 150 000	AQL = 0.25	AQL = 1.0
Acceptance of the batch in the case of….defective items out of…condoms tested	0 out of 200 3 out of 400	2 out of 125 6 out of 250
Rejection of the batch in the case of…or more defective items out of…condoms tested	3 out of 200 4 out of 400	5 out of 125 7 out of 250

Tests on larger batches are possible; the sampling plans and tables to be used must be agreed in writing (using the same inspection level according to ISO 2859-1)

Testing at an approved testing laboratory:
The testing laboratory at which the User has the tests carried out will be agreed in writing. The exact designation of the laboratory must be given. The test in accordance with the Regulations (Section 4) must be guaranteed and the laboratory must be prepared to take part in regular interlaboratory tests carried under the lead of the Awarding Body in order to guarantee the data. The testing laboratory has to be accredited in accordance with EN45001 for the testing of condoms, the accreditation of which must be recognised by the EA, the European co-operation for Accreditation.

In exceptional cases the Awarding Body for the Quality Seal may accept the test reports of the manufacturer. In this case it is required that a sufficient number (at least 1'000) of samples for retesting are retained, that the testing laboratory participates regularly at interlaboratory round robin tests, and that the results of those interlaboratory tests are communicated to the Awarding Body for the Quality Seal. The Awarding Body for the Quality Seal may cancel this permission with 3 months notice in case of documented irregularities.

The test results for each batch are to be made available regularly by the testing laboratory to the Awarding Body for the Quality Seal in the form of electronically readable files. The format of the data is to be agreed with the Awarding Body.

6.2 Batches that are designated to be distributed to the final user free of charge with the aim of prevention.

If such batches carry the CE-mark, are tested according to these regulations and those test results are communicated according to sections 4.3 and 6.1 to the Awarding Body for the Quality Seal, then such batches may carry the Quality Seal for Condoms if they conform to the requirements according to sections 4.1 and 6.1, irrespective of the fact that they are isolated batches. The organization, the name of which appears on the package, is responsible that the test results are communicated to the Awarding Body for the Quality Seal. In addition the envisaged channels of distribution have to be communicated. A contract has to be signed between the organization, the name of which appears on the package, and the Awarding Body for the Quality Seal. Such contract, however, is not required between the manufacturer and the Awarding Body for the Quality Seal.

6.3 Batches that are designated to be distributed to the final user with the aim of promotion.

If such batches carry the CE-mark, are tested according to these regulations entirely or partially and those test results are communicated according to sections 4.3 and 6.1 to the Awarding Body for the Quality Seal, then such batches may carry the Quality Seal for Condoms, even if they conform only to the requirements of EN ISO 4074, irrespective of the fact that they are isolated batches. The organization, the name of which appears on the package, is responsible that the test results are communicated to the Awarding Body for the Quality Seal. In addition the envisaged channels of distribution have to be communicated. A contract has to be signed between the organization, the name of which appears on the package, and the Awarding Body for the Quality Seal. Such contract, however, is not required between the manufacturer and the Awarding Body for the Quality Seal. This special regulation is only available to members of the Verein «Gütesiegel für Präservative» (Association for the Quality Seal for Condoms). Usually a fee for the attachment of the Quality Seal will be paid to the Awarding Body. The amount of that fee will be decided on for each case in mutual agreement with the managing board of the Verein «Gütesiegel für Präservative» (Association for the Quality Seal for Condoms).

7 Supervision

The User must grant the Awarding Body access to the business documents in which the size of each batch of condoms and their provenance are made clear. The Awarding Body regularly takes market samples and has them tested at its own expense and, by means of statistical analysis, establishes on the basis of the test results whether the condoms sampled come from the original batch tested (for the method of statistical analysis see the Appendix of 30 March 2004)

The Awarding Body does not regularly control the compliance of condoms with the MepV. If there is good reason to suspect that there have been breaches of the MepV, the Awarding Body informs the official control bodies.

The general assembly of the members of the Verein «Gütesiegel für Präservative» (Association for the Quality Seal for Condoms) will be annually informed of which manufacturers have submitted their own test results according to section 6.1, and how many batches were awarded the Quality Seal for what actions according to sections 6.2 and 6.3.

8 Award of the Quality Seal

Authority to use the Quality Seal may be given if the potential User makes a contractual undertaking

8.1 to sell only tested batches of eligible brands meeting these Regulations in Switzerland. If there are various types of the same brand, all types must meet the conditions of the Quality Seal;

8.2 to use the Quality Seal only for batches which have passed the test in accordance with the Regulations (this also applies to batches which are not destined for the Swiss market, but which carry the Quality Seal);

8.3 to pay the licence fee and bear the costs of supervision (in accordance with Section 12);

8.4 to withdraw a batch from the market if the results from the condoms sampled from the markets according to statistical analysis (see Appendix, section A.4) do not match those which were originally tested, although they bear the same batch number, and which, with regard to bursting pressure and burst volume, do not meet the requirements of Section 4.1 with an AQL of 1.5 (for calculation, see Appendix, Section A.5), disregarding the requirement for a minimal average bursting volume. The Arbitration Tribunal (Section 11) decides whether they must be recalled following an application made by the Awarding Body. Before the Awarding Body makes this application to the Arbitration Tribunal, it will attempt

to come to an agreement with the User. Ascertaining the causes of the established deviations from the requirements has priority;

8.5 to make condoms for interlaboratory tests available free of charge;

8.6 to inform the Awarding Body of the numbers of condoms sold in Switzerland by 31 March of the following year

The following conditions also apply

8.7 Until a relationship of trust has been established, the Awarding Body may demand that it organises sampling itself, with the (potential) User bearing the additional occurring costs. This regulation normally applies for the first 5 batches per type of condom. If more than two of these 5 batches do not meet the requirements of these regulations (section 4), an unbroken series of 5 batches must meet the requirements before the User may carry out the sampling himself in accordance with Section 5. The Awarding Body may require at any time that it undertakes the sampling itself.

8.8 When application is made for the testing of condoms for the award of the Quality Seal, the customer releases the testing laboratory of its duty for confidentiality. The testing laboratory is entitled to pass on all findings to the Awarding Body.

9 Disqualification from using the Quality Seal

The Awarding Body has the right to apply to the Arbitration Tribunal to withdraw permission to use the Quality Seal, if any of the following cases arise:

9.1 If untested batches bearing the Quality Seal are put on the market.

9.2 If, within one year or in 10 batches (whichever gives the higher number of batches) out of the supervised market sample in accordance with Section 7 and using statistical analysis, two batch numbers are found for which the results of the original condoms sampled and those sampled from the market do not agree, although they bear the same batch number, irrespective of whether the condoms sampled from the market meet the requirements of the regulations (Section 4) or not.

9.3 If any of the conditions of Section 8 is not met.

9.4 If the Awarding Body has some other justified reason to withdraw its trust from the User.

10 The Quality Seal

10.1 The Quality Seal has the following appearance and is registered with the Bundesamt für geistiges Eigentum (Federal Office for Intellectual Property) in accordance with Art. 7bis of the Trade Mark Protection Law (systematic collection of Federal Law Nr. 232.11):

10.2 The Quality Seal may be used by the User on single packets, consumer packages, packaging leaflets, brochures and in advertising. A sample copy of each use of the Quality Seal is to be sent to the Awarding Body.

The Quality Seal may be affixed to packaging only if, on a packaging leaflet, for instance, an explanatory note with the following content is attached: “The requirement for the award of the Quality Seal for Condoms is a test of each batch in accordance with the regulations of the Verein Gütesiegel für Präservative (Association for the Quality Seal for Condoms) which supervises the quality testing”.

11 The Arbitration Tribunal

11.1 The exclusive task of the Arbitration Tribunal is to rule on applications by the Awarding Body with regard to the withdrawal of batches and disqualification from the right to use the Quality Seal. If there is any doubt as to the results from the testing institute, the usual legal action is to be taken.

11.2 The Arbitration Tribunal consists of the following three members:

a) a neutral president.

b) a person designated by the User, but who is not employed by him.

c) a person designated by the awarding body.

11.3 As a rule, the neutral president will be designated by agreement between the other two members of the Arbitration Tribunal. If they cannot agree, he/she will be appointed by the Commercial Court of Zurich.

11.4 The Arbitration Tribunal will reach its decisions by simple majority after hearing the company involved and any expert witnesses summoned. Each member has one vote. Abstention is permissible. In the event of an equal division of votes, the Awarding Body's application is considered to be rejected.

12 Costs

The User is liable to pay the following costs:

- per brand bearing the Quality Seal, the annual licence fee for the use of the Quality Seal (The Association covers its basic costs [secretarial and administrative] with the licence fee).
- per batch that the User puts into circulation, the supervision fee (with the supervision fee, the Association covers its costs for market-sampling [purchase of condoms] and the tests thereof)
- expenditure for sampling at the location of the User (working time and travelling costs of the appointed persons, according to expenditure as agreed).
- expenditure for visits by the Awarding Body to the User's production, packing and testing sites in the case of established irregularities (working time and travelling expenses of the appointed person, according to expenditure as agreed)

The prices for the licence and supervision fees may be adapted by the Verein Gütesiegel für Präservative (Association for the Quality Seal for Condoms) without any alteration to the Regulations. Users will be informed of new prices in such a way that they have the opportunity to terminate the User contract when the new prices come into force.

13 Head Office of the Awarding Body for the Quality Seal

The registered head office is as follows:

Verein Gütesiegel für Präservative
Hirschmattstrasse 47
CH-6003 Lucerne
Switzerland

14 Final provisions

These Regulations dated 11 May 2011 together with the Appendix dated 30 March 2004 were agreed by the members of the Verein Gütesiegel on 11 May 2011 and replace all previous Regulations and Appendices.