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Regulations Relating to the Quality Seal for Additional Products Compatible to Condoms

Lucerne, 08 May 2008

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The requirements at a glance

- Producers, packing agents or importers may use the Quality Seal for Additional Products Compatible to Condoms if they agree by contract to fulfil all parts of this Regulations and, if such products are sold or distributed together with condoms, to ensure that these condoms bear the Quality Seal for Condoms.
- The product must be tested by an independent accredited laboratory in the described manner before released for sale and every second year thereafter. The accreditation of the laboratory must be recognised by the EA, the European Co-operation for Accreditation.
- The product must not significantly change the bursting properties of condoms as measured by the described evaluation of the test.
- The composition of the product must be deposited with the Verein Gütesiegel für Präservative.
- The Verein Gütesiegel für Präservative ensures that the Regulations are observed by taking market samples to be tested at its discretion.

All details are covered by the following Regulations Relating to the Quality Seal for Additional Products Compatible to Condoms.

1. Purpose of the Quality Seal

- Products like lubricants, topical medications, foams, etc. may come in contact with condoms during use and my cause a deterioration of the condom. Such deterioration may facilitate the transmission of infections or unwanted pregnancies.
- The Quality Seal denotes products which do not adversely affect condoms, specifically those made of natural rubber latex. If so tested, it may be stated that these products also do not adversely affect condoms made from other materials.
- The Quality Seal for Additional Products Compatible to Condoms helps consumers to choose a good quality product from amongst those on the market. It guarantees that the product does not adversely affect condoms during use.

2. Scope

The Quality Seal applies to products sold in Switzerland. The sale of these products so designated is allowed in other countries too. It is not allowed to designate such products with the Quality Seal if they are marketed only outside of Switzerland.

3. Definitions

3.1 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 14).

3.2 Users of the Quality Seal

Producers, packing agents and importers of products that may come in contact with condoms during use 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.

4. Requirements

4.1 General

The prerequisite for the granting of the Quality Seal is compliance with the relevant official Swiss regulations for the specific product (medication, cosmetic product, etc.). The Verein Gütesiegel für Präservative (Association for the Quality Seal for Condoms) assumes that those official regulations are met when the product is presented. The Users of the Quality Seal have to confirm this by accepting the corresponding section of its contract with the Verein Gütesiegel für Präservative.

4.2 Composition

The User must declare the composition of the product and guarantee to keep the composition constant. If any change of the composition is made, this has to be communicated to the Verein Gütesiegel für Präservative and the tests for the product have to be repeated immediately, commissioned by the User.

4.3 Compatibility with condoms

When tested with natural rubber latex condoms according to section 6, the evaluation according to section 7 must not show any significant change of the bursting properties of condoms. If compatibility with condoms made from other materials is clamed, the product has to be tested with those condoms too.

4.4 Associated condoms

If the product is sold or distributed together with condoms, these condoms must bear the Quality Seal for Condoms.

5. Sampling

A representative sample of the product is to be drawn by the User of the Quality Seal and sent to the testing laboratory. If the product is sold or distributed together with certain condoms, condoms of that type have to be also sent to the testing laboratory. Otherwise the testing laboratory chooses

appropriate condoms at its discretion, preferably condoms without lubrication. If the condoms sold or distributed together with the product are not made from natural rubber latex, the testing laboratory chooses appropriate natural rubber latex condoms at its discretion in addition.

6. Application of the product and measurements

Place the product (about 0,5 g) in the condom. If the product is meant to be applied diluted (such as foaming agents), do not use the pure product but dilute it first to the five fold concentration of its intended application and place about 0,5 g of that solution in the condom. Roll the condom on a big test tube (diameter 38 ± 2 mm) so that the product or solution is spread between the test tube and the condom. Place the tube in a water bath at 37 ºC for 1 h. Remove one condom at the time from the water bath, remove it from the test tube and test it for bursting properties immediately. All condoms have to be tested within 1,5 hours after they have been placed in the water bath.

Do this with 25 condoms. Another 25 condoms are treated in the same way but without the additional product or solution.

If more than one type of condoms has to be used for the test, repeat the test with each additional type of condoms.

7. Evaluation

For each type of condoms used in the test proceed as follows:

Remove the results of any condom whose bursting pressure or bursting volume is smaller than the respective mean value minus two standard deviations. Recalculate the new mean values. The analysis is done separately for bursting volume and bursting pressure.

The scale of values is divided into four classes:

smaller than m – 0,85s; m – 0,85s to m; m to m + 0,85s; Greater than m + 0,85s

where m = average value of the condoms without the additional product

s = standard deviation of the condoms without the additional product

The number of values in each class is counted and the testing value X^2 is calculated according to the following formula (chi square test with samples from multinomial populations)

$$X^2 = (n_1 + n_2) \cdot (-1 + \frac{1}{n_1 n_2} \cdot \sum_{j=1}^{k} \frac{n_2 b_{1j}^2 + n_1 b_{2j}}{b_{1j} + b_{2j}})$$

where n1 = number of condoms without the additional substance

n2 = number of condoms with the additional substance

k = number of classes (= 4)

b1j = frequency of condoms without the additional substance, in class j

b2j = frequency of condoms with the additional substance, in class j

If the testing value X^2 for bursting volume and/or bursting pressure is greater than or equal to 6,25 (limiting critical value of chi square for a distribution with 3 degrees of freedom and a threshold of tolerance for error of 10 %), one can assume that the tested product adversely affects the condoms.

The product has passed the test if no type of condoms used show an indication that the product adversely affects them.

8. Supervision

The User must grant the Awarding Body access to the business documents in which the composition of the product and its provenance is made clear. The Awarding Body may take market samples at its discretion and have them tested at its own expense.

9. Award of the Quality Seal

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

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

9.2 to use the Quality Seal only for products which have passed the test in accordance with the Regulations (this also applies to products which are destined for outside the Swiss market too);

9.3 to pay the licence fee and bear the costs of supervision (in accordance with Section 13);

9.4 to use the Quality Seal on products which are marketed outside Switzerland only when those products are marketed in Switzerland too;

9.5 to report the amount of products with the Quality Seal sold in Switzerland and outside of Switzerland and in which countries;

9.6 to withdraw a product from the market if the results of the tests show that it does not meet the requirements of Section 7. The Arbitration Tribunal (Section 12) decides whether it 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.

9.7 When application is made for the testing of products for the award of the Quality Seal, the User releases the testing laboratory of its duty for confidentiality. The testing laboratory is entitled to pass on all findings to the Awarding Body. The User commissions the testing laboratory to send all relevant test results to the Awarding Body.

10. 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:

10.1 If any of the conditions of Section 4 is not met.

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

11. The Quality Seal

11.1 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):

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

12. The Arbitration Tribunal

12.1 The exclusive task of the Arbitration Tribunal is to rule on applications by the Awarding Body with regard to the withdrawal of products 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.

12.2 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.

12.3 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.

12.4 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.

13. Costs

The User is liable to pay the following costs:

- per brand of product 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). If the User already is entitled to use the Quality Seal for Condoms with the same brand name, the annual licence fee may be waived.
- per product that the User puts into circulation, the supervision fee (with the supervision fee, the Association covers its costs for market-sampling [purchase of product] 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) if such sampling seems necessary due to noticed irregularities.
- 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 price for the licence fee 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 a new price in such a way that they have the opportunity to terminate the User contract when the new price comes into force.

14. 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

15. Final provisions

These Regulations were agreed by the members of the Verein Gütesiegel on 08 May 2008.