



**Quality and test regulations
for
condoms made from natural rubber latex**

version August 2009

Deutsche Latex Forschungsgemeinschaft Kondome e.V.



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These quality and test regulations were developed in conjunction with "Deutsche Latex Forschungsgemeinschaft Kondome e.V." and "Staatliche Materialprüfungsanstalt Darmstadt" to form the basis for quality assurance of condoms made from natural rubber latex.

Rotenburg, March 2009

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1 Preface

These quality and test regulations were developed in conjunction with Deutsche Latex Forschungsgemeinschaft Kondome e.V. and Staatliche Materialprüfungsanstalt Darmstadt to form the basis for quality assurance.

The following regulations are intended for guaranteeing and monitoring the quality characteristics of condoms made from natural rubber latex with the purpose of being worn on a fully erected penis to act as a mechanical barrier during sexual relations (hereunder designated as "condom").

The testing of the manufacture of condoms (production) and the testing of condoms (product) is carried out on the basis of a framework contract between Deutsche Latex Forschungsgemeinschaft condoms e. V. (designated DLF hereunder) and Staatliche Materialprüfungsanstalt Darmstadt (designated MPA-DA hereunder) according to the quality and test regulations below.

The user of the quality mark (manufacturer of condoms, moulder of the "raw products" or marketing organisation) has undertaken by virtue of a monitoring contract to comply with the regulations below and to guarantee a uniform high quality of the condoms through careful monitoring of production.

2 Scope, Designation

The quality and testing regulations only apply to those condoms whose compliance with Technical Regulation DIN EN ISO 4074¹ has been declared.

Quality assurance covers the manufacture of condoms (raw products) and the moulding of the raw products as well as packaging procedures for the condoms.

These regulations govern in-house and external controls of condoms made of natural rubber latex (latex)², which are marked with the "Quality mark DLF".

They only apply to certain designs of condoms listed in DIN EN ISO 4074 which are manufactured

continuously in a dipping procedure and have a uniformly thickened edge at the open end.

The quality and test regulations cover the investigations which enable an evaluation of the condoms to be made in terms of the maintenance of a uniformly good quality on the basis of physical and microbiological characteristics.

3 Quality regulations

The standard DIN EN ISO 4074 applies to condoms. The requirements of this standard shall be met.

In addition ISO 29941³ applies; because of missing requirements no assessment of results are indicated⁴.

In addition, the following **requirements** apply:

3.1 General requirements

3.1.1 Requirements of the packaging material

Interactions between packaging material, the material and surface coating of the condom shall not affect the intended use.

If the surface of the packaging materials is coated there shall be no "bleeding" of the printing inks.

3.1.2 Requirements of production

Production should be organised so that the intended use is ensured from the prophylactic, hygienic and chemical-toxicological point of view and a quality of the individual product is maintained which satisfies the requirements for use.

A guideline is provided by "Good Manufacturing Practice for Medicines (GMP) and Medicinal Products".

3.2 Special requirements

The condoms are tested in accordance with the international standard DIN EN ISO 4074; the condoms should satisfy the requirements of this standard.

¹ DIN EN ISO 4074 Condoms made of natural rubber latex – requirements and testing procedures“ in the respectively valid version

² Definitions in DIN 53501 (withdrawn)

³ ISO 29941 Condoms – Determination of nitrosamines migrating from natural rubber latex condoms into various media
in the respectively valid version (at present DIS 29941)
⁴ see page 5, table 2, nitrosamines

In addition to the international standard, the following requirements apply to **quality-assured** condoms:

3.2.1 Requirements of the general condition which can be visually inspected

In addition to the test "Visible defects" in accordance with DIN EN ISO 4074 para. 9, when inspecting condoms in accordance with section 4.1 they shall not present any other visible defects such as bubbles, tears, inclusions, contamination or conglutination.

3.2.2 Requirements of the wall thickness

For condoms whose thickness is not indicated, the wall thickness shall be in the range of 0.04 mm to 0.08 mm.

3.2.3 Requirements of microbiological purity

When testing according to section 4.7, no enterobacteria, no *Pseudomonas aeruginosa*, no *Staphylococcus aureus* and max. 10^3 (in individual cases 5×10^3) aerobic bacteria should be contained in 10 ml of extraction liquid (corresponding to 1 g sample material).

3.2.4 Requirements of the force at break

Condoms, which do not have any special strength shall have a force at break which satisfies the requirements of table 1.

3.2.5 Requirements of the tensile strength

The tensile strength shall satisfy the requirements of table 1.

Note:

The tensile strength σ_R is the quotient of the force F_R measured at the moment of tearing (force at break) and the initial cross-section A_0 of the test specimen, determined with the wall thickness according to section 4.2.

3.2.6 Requirements of the elongation at break

The elongation at break shall satisfy the requirements of table 1.

Table 1: Force at break, tensile strength and elongation at break as a function of ageing

Property	Requirements		
	Untreated condoms up to max. 1 year after manufacture	Heat treated condoms up to max. 1 year after manufacture	After natural ageing of more than 1 year after manufacture
Force at break in N	≥ 39	≥ 39	≥ 39
Tensile strength in N/mm ²	≥ 20	≥ 17	≥ 17

Elongation at break in %	700	700	700
* Applies to condoms, whose dipping manufacturing date is more than 12 months old at the time of this test.			

4 Testing regulations

Unless specially specified the condoms are tested in accordance with DIN EN ISO 4074. The size of random samples for in-house production controls and outside monitoring is defined in accordance with DIN EN ISO 4074, Annex A and for initial testing and repeat testing in accordance with DIN EN ISO 4074, Annex B.

The requirements of this standard shall be met.

In addition, the inspections defined in table 2 apply with the specifications indicated for random sampling.

4.1 General condition which can be visually inspected (Visual inspection)

The condoms are subjected to visual inspection with normal or corrected visual acuity.

4.2 Wall thickness

The wall thickness is determined in accordance with DIN 53 534 on annular specimens in accordance with DIN EN ISO 4074, Annex I.

The inspection is carried out with a thickness gauge with mechanical measurement and mechanical transmission of the measurement values (dial gauge) or at least equivalent testing equipment.

The measurement surfaces consist of the plane supporting surface as well as the circular plane measurement surface at the foot of the callipers (diameter preferably 10 mm).

The measurement pressure should be (22 ± 5) kPa.

Before making the measurement, the coating of the condoms to be tested is removed by briefly immersing in a suitable cleaning agent (e.g. isopropanol) and subsequent wiping with a soft, absorbent cloth.

At least 5 individual determinations are made on one condom evenly distributed over the circumference and the median indicated in accordance with DIN 53598-1:1983-07 Statistical Evaluation on Random Samples with Examples from Elastomer and Plastics Testing.

4.3 Force at break

The test is carried out in accordance with DIN EN ISO 4074, Annex I, selecting condoms with at least 20 mm length of cylindrical shaft.

4.4 Tensile strength

The tensile strength is determined from the force at

break according to section 4.3 and the wall thickness according to section 4.2.

4.5 Elongation at break

The elongation at break is determined in accordance with DIN EN ISO 4074, Annex I, para. I.5.2, selecting condoms with at least 20 mm length of cylindrical shaft.

4.6 Oven treatment

Oven treatment should only be applied to condoms which are not older than 1 year from the date of manufacture. The heat treatment involves storing the condoms in their individual packs in an oven for (168 ± 2) h at (70 ± 2) °C according to the procedure described in DIN EN ISO 4074, Annex H.

4.7 Microbiological Purity

The microbiological purity is tested according to the indications in the European Pharmacopoeia (Ph. Eur. 2008, para. 2.6.12) by counting the total number of viable, aerobic bacteria on Agar plates (poured plate process).

The condoms should be taken from the packs under aseptic conditions. 10 g sample material are cut up with sterile scissors and shaken for (5 to 10) minutes on the mechanical rocker at approx. 1 000 rpm in 100 ml of a suitable liquid (e.g. sodium chloride peptone buffer solution [pH 7.0]) with the addition of glass beads. The extracted liquid should not have any antimicrobial properties. If necessary, before use it should be provided with appropriate additives (e.g. 3 % polysorbate 80 and 0.3 % lecithin). 10 ml is taken from the extracted liquid to check for the presence of the above-mentioned pathogenic bacteria. 1 ml of the extracted liquid is used to count the total number of viable aerobic bacteria.

5 Monitoring

In order to ensure that the number of random samples and individual inspections have a reasonable relationship to the overall production, in accordance with these quality and testing regulations, the following tests and monitoring operations are undertaken.

Monitoring operations are classified as:

- Initial testing
- In-house production controls
- Outside monitoring
- Repeat testing

For the initial testing, outside monitoring and repeat testing, the DLF contracts a state owned, recognised, accredited inspection institute⁵ or suitable experts.

The costs of inspection are borne by the applicant for the initial testing and the user of the quality mark for outside monitoring and, if necessary for

repeat testing.

5.1 Initial testing (IT)

Every manufacturer of condoms, who has applied to the DLF for the quality mark to be awarded, must subject products which will carry the quality mark to initial testing.

As part of initial testing, the MPA-DA inspection engineer makes sure by making a works visit that the applicant guarantees by means of their equipment and technical staff that these quality and test regulations are constantly being observed.

The MPA-DA inspection engineer takes officially the relevant number of test specimens (condoms) for testing in accordance with section 4 of these quality and test regulations from the products at the applicant's which are intended to be provided with the quality mark.

5.2 In-house production control (Ihpc)

The user of the quality mark should constantly monitor the quality of their products by carrying out their own controls.

They should ensure themselves that these quality and testing regulations are satisfied at all times.

The quality mark user is obliged to make records of the continuous Ihpc to be carried out, to record the test results on appropriate forms and to keep the records for at least 6 years. These records should be submitted to the inspector as part of external monitoring.

If the production process is changed additional appropriate controls must be carried out for quality assurance and the results recorded on appropriate forms.

In-house Ihpc by the user of the quality mark covers all phases of further processing of the delivered raw products (condoms) as well as packaging operations, in particular

- definition of and compliance with all quality characteristics and product requirements,
- early or prompt detection of existing defects as well as
- prompt and effective measures to eliminate these defects.

In order to provide reliable traceability of product properties and manufacturing characteristics the products are classified in batches in accordance with DIN EN ISO 4074, para 3.8.

In order to ensure a uniform high quality of the products, the tests listed under section 4 of the quality and testing regulations should be carried out on each batch.

5.3 Outside monitoring (OM)

Outside monitoring by the MPA-DA inspection engineer is carried unannounced and covers the verification of the quality assured products of the user of the quality mark in accordance with these quality and testing regulations.

⁵ Staatliche Materialprüfungsanstalt Darmstadt, Kompetenzfeld Medizintechnik, Grafenstraße 2, 64283 Darmstadt, Germany, hereunder designated as MPA-DA, DAR-Reg.No. ZLG P-977-95-01

The records of the in-house controls carried out by the user of the quality mark should be submitted to the inspector.

Official sampling of the test batch by the MPA-DA inspector is carried at least once a year, unannounced with the required scope.

Sampling is carried out in the presence of the company owner, his representative or nominee.

Sampling covers all sales goods provided with the quality mark. Products which have been designated by the user of the quality mark as defective (rejects) may only be excluded from sampling if they are clearly marked as such and stored separately.

The MPA-DA reports on the results of the outside monitoring by means of the following documents:

- Visit report

The MPA-DA inspector produces a report on the visit to the user of the quality mark. On request, a copy is sent to the DLF office.

- Test certificate

The MPA-DA inspector summarises the test results in a test certificate. The quality mark user receives a copy and the DLF office another one after consultation.

5.4 Repeat testing (RT)

If during outside monitoring one or more tests are assessed by MPA-DA as negative with results not complying with the requirements, repeat testing will be carried out. The user of the quality mark will be required to immediately eliminate the defects by means of notification of the negative assessment of one or more tests in the MPA-DA test certificate, so that as a rule the sampling for the repeat testing can be made within 4 weeks after notification of the negative assessment.

The sampling for the repeat testing by the MPA-DA inspection engineer is carried out unannounced with the required scope.

The user of the quality mark must provide evidence of elimination of the defects under contention.

If the repeat testing is also not passed because of essential defects, the outside monitoring is considered not to have been passed as a whole. Subsequent procedures will be governed by the implementation regulations for awarding and using the condom quality mark.

6 Subcontractors

Insofar as parts of the production are carried out by subcontractors, the subcontractor should also satisfy the prerequisites for using the quality mark.

7 Marking with the quality mark

Condoms which comply with these quality and test regulations are provided with the adjacent illustrated quality mark on the packaging as soon as the quality mark has been awarded and the prescribed requirements of these quality and test regulations are satisfied.



The application and use of the quality mark is governed exclusively by the Regulations on the Use of Marks in its currently valid version.

Product designs provided with the quality mark must be notified to the Deutsche Latex Forschungsgemeinschaft Kondome e. V. (DLF) before the product concerned is placed on the market.

8 Amendments

Amendments to these quality and test regulations require the written consent of Deutsche Latex Forschungsgemeinschaft Kondome e.V. They will only be put into effect by the DLF board after an appropriate period of time, i.e. after notification to the user of the quality mark.

Table 2: Sample size and requirements

Test	Test guidelines	Test level	Random sample size		AQL	Acceptance no. c		Requirement / Characteristic
			lhpc/OM ¹⁰	IT/RT		lhpc/OM	IT/RT	
Lubrication ²	ISO 4074	./. ¹	13	13	./.	./.	./.	according to indication on the user pack
Length	ISO 4074	./. ¹	13	13	./.	./.	./.	Individual value ≥ 170 mm
Width	ISO 4074	./. ¹	13	13	./.	./.	./.	Nominal width ± 2 mm
Thickness ³	ISO 4074	./. ¹	13	13	./.	./.	./.	= nominal thickness
	G+P ⁹	S-2	13	13	4,0	1	1	(0.04 - 0.08) mm
Bursting volume and bursting pressure of untreated condoms	ISO 4074	I	200 ⁶ / 315 ⁷	315 ⁸ / 315 ⁷	1,5	7 ⁶ / 10 ⁷	10	≥ 1 kPa (2 kPa ⁴) 16 dm ³ (b < 50 mm) 18 dm ³ (50 mm \geq b < 56 mm) 22 dm ³ (b \geq 56 mm)
Force at break ⁵ , Tensile strength, Elongation at break of untreated condoms	ISO 4074	./. ¹	13	13	./.	./.	./.	Mean > 100 N
	G+P	S-2	13	13	4,0	1	1	> 39 N; ≥ 20 N/mm ² ; ≥ 700 %
Force at break, Tensile strength, Elongation at break of oven-treated condoms	G+P	S-2	13	13	4,0	1	1	> 39 N; ≥ 17 N/mm ² ; ≥ 700 %
Freedom from holes	ISO 4074	I	315 ⁸ / 315 ⁷	500 ⁸ / 500 ⁷	0,25	2	3	Free of holes
Visible defects	ISO 4074	I	315 ⁸ / 315 ⁷	500 ⁸ / 500 ⁷	0,4	3	5	No folding, no "defective" roll-on edge
General condition which can be visually inspected	G+P	I	315 ⁸ / 315 ⁷	500 ⁸ / 500 ⁷	1,5	10	15	No visible damage (total number)
Packaging and labelling	ISO 4074	./. ¹	13	13	./.	./.	./.	according to DIN EN ISO 4074, para. 11
Microbiological purity	G+P	./. ¹	13	13	./.	./.	./.	$\leq 10^3$ KBE/g (in individual cases $\leq 5 * 10^3$ KBE/g)
nitrosamines ¹¹	ISO 29941	./. ¹	13	13	./.	./.	./.	No requirements at the moment

¹ no attribute testing according to DIN ISO 2859-1

² Only carry out testing if amount of lubricant indicated on Vp

³ if nominal thickness indicated, testing according to DIN EN ISO 4074, otherwise according to G+P

⁴ for especially strong condoms

⁵ when testing according to ISO only the tensile strength is tested and only for especially strong condoms

⁶ applies to batch sizes from 35,001 to 150,000

⁷ applies to batch sizes from 150,001 to 500,000

⁸ applies to batch sizes from 35,001 to 150,000 (according to DIN ISO 2859-1) at least code letter M

⁹ Quality and Test Regulations for condoms made from natural rubber latex

¹⁰ Applies to continuous production relationships ≥ 5 batches according to DIN EN ISO 4074:2002-07

¹¹ quality mark user shall test one product per year each