Medical Compression Hosiery

Quality Assurance RAL-GZ 387/1

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Sankt Augustin, January 2008

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Implementation Guidelines for the Award and Use of the Quality Mark for Medical Compression Hosiery

Quality and test specifications for medical compression hosiery

1 Scope

These quality and test specifications apply to medical compression hosiery, but do not apply to support and thrombosis prophylaxis hosiery.

These quality and test specifications will be supplemented and updated in line with technical advances and industry standards.

2 Terms and definitions

2.1 Extensibility

Change in size of the hosiery in longitudinal or transverse direction when stretched, expressed as a percentage ratio to the size of the hosiery when in a non-stretched condition.

2.2 Pressure profile

Representation of the compression exerted by the hosiery along the leg.

2.3 Inlaid thread

Elastic thread that does not form stitches or loops inlaid in the direction of the course.

2.4 Elastic material

Material that increases in size under tensile force and returns virtually to its original form when the force is removed.

2.5 Elastic thread

Stitch forming thread with rubber-elastic behaviour.

2.6 Elasticity characteristic

Change in compression in hPa under the hosiery at a specific measuring point with an increase in the leg circumference by 1 cm.

2.7 Unit of linear density

Ratio of the mass to the length of a yarn. The unit of measure is tex.

Normally expressed in dtex (1 dtex = 0.1 g/1000 m).

2.8 Rubber-elastic behaviour

Property of a material based on the elastic principle of elastodiene (rubber) or elastane (designations according to DIN 66001, part 1).

2.9 Rubber thread count

Number of threads which, when placed side by side, are 25.4 mm in width.

2.10 Compression

Pressure exerted on the leg by compression hosiery

2.11 Compression classes

Compression grades in which hosiery is manufactured according to specific medical requirements. The pressures based on the compression classes refer to the ankle area (measuring point b).

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Compression hosiery individually manufactured according to specific leg dimensions.

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2.16 Standard size hosiery

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2.17 Tolerance of standard size hosiery

Leg circumference and length limits within which standard size hosiery provides the required compression.

2.18 Two-way stretch compression hosiery

Medical compression hosiery having rubber-elastic properties due to the special knitting construction in longitudinal and transverse direction.

3 Requirements

3.1 General

3.1.1 Manufacture

It must be ensured in the design and manufacture of the hosiery that the risks of substances being released by the product are reduced to a minimum.

Verification according to sub-clause 4.3

3.1.2 Packaging

The packaging used by the manufacturer for standard size hosiery must be designed to protect hosiery from soiling and light.

Test according to sub-clause 4.1

3.2 Design

3.2.1 Knitting construction

Medical compression hosiery with the quality mark can be manufactured in the following knit types:

3.2.1.1 Flat bed knitted hosiery with seam, formed by knitting with a minimum of one knitted and one inlaid rubber-elastic thread in every second course.

3.2.1.2 Single and double face, seamless hosiery, formed by knitting with a minimum of one knitted and one inlaid rubber-elastic thread in every second course.

Test according to sub-clauses 4.1 and 4.4.3.3

3.2.2 Design

3.2.2.1 Heel

The hosiery must have a closed and knitted, rubber-elastic heel with appropriate anatomic form. The hosiery type according to sub-clause 3.2.1.2 must be knitted with a reciprocated heel.

Test according to sub-clause 4.1

3.2.2.2 Seams

All seams must be without bulges on the leg. The seams must be durable and have a professional finish.

Test according to sub-clause 4.1

3.2.2.3 Edges

Edges must be clean, e.g. linked, edged.

Test according to sub-clause 4.1

3.2.2.4 Toes

The hosiery can be manufactured with or without open toes.

3.2.3 Forming

Forming of the compression hosiery to the leg must not take place by chemical finishing or heat, but by knitting. Smoothing for presentation purposes is permitted.

Test according to sub-clause 4.1 and verification according to sub-clause 4.2.

3.3 Materials

3.3.1 General

Only materials and dyestuffs are to be used that are unharmful to humans. In particular, these materials must not contain azo dyestuffs that can separate carcinogenic amines, allergenic disperse dyestuffs and pesticides The limits for nickel and formaldehyde must be observed. The pH value must be between 5 and 7.

Test according to sub-clause 4.3

Determination of fibre content according to sub-clause 4.4

3.3.2 Textile course

Threads of natural or chemical fibres can be used.

3.3.3 Elastic thread and weft thread

3.3.3.1 Rubber-elastic threads

Threads of elastodiene (rubber) or elastane can be used.

Test according to sub-clause 4.4.2

3.3.3.2 Covering

Rubber-elastic threads must be covered with natural or chemical fibres. The processes shown in Table 2 can be used. Weft threads of elastane can remain uncovered.

Test according to sub-clauses 4.1 and 4.4.3.3

Note: The recommendations of the manufacturers of elastane and elastodiene in respect of the maximum elongation of the core thread when covering must be observed, as the elongation has a considerable influence on the durability of the elastic thread.

3.3.3.3 Thread linear density

The thread thickness must correspond to the values shown in Table 1 (annex).

Test according to sub-clause 4.4.3

3.4 Types of hosiery

Preferably manufactured are the types of hosiery shown in Table 3 appropriate to the areas of the leg to be treated. The designations are based on the measuring points defined in Fig. 1. Other types of hosiery are possible.

3.5 Hosiery sizes

3.5.1 Custom-made hosiery

Manufacture takes place individually according to the leg circumference and length.

3.5.2 Standard size hosiery

Manufacture takes place in standard sizes as indicated by the measuring points along the circumference and length of the leg as shown in Fig. 1.

3.5.2.1 Hosiery sizes and lengths

The leg circumferences, taken as a basis, are shown in each column in Table 4, the leg lengths and ranges of length are shown in Table 5.

Other leg size combinations can also be used.

3.5.2.2 Designation of the hosiery type and size during manufacture must take place according to the leg sizes shown in Tables 4 and 5.

The type code consists of a code for the hosiery type (according to Table 3), followed by three sets of numbers. These indicate the leg sizes for which the hosiery is intended:

a) Circumference at the ankle (measuring point B)

b) Circumference at the upper end of the hosiery (measuring points D, F or G).

c) Range of length (based on the total length of the respective hosiery type).

The values relating to the hosiery type and circumference at the ankle must be emphasised.

The examples below clearly show the type code:

Example 1: **AD 22-24** (34-36 / 40-43)

Where the following are:

AD: Code for below knee hosiery
22-24: Leg circumference at measuring point B (22-24 cm)
34-36: Leg circumference at the upper end of the hosiery (here measuring point D: 34-36 cm)
40-43: Range of length (here AD: 40-43 cm)

Example 2: **AF 20-23** (46—50 / 57-64)

Where the following are:

AF: Code for mid-thigh hosiery
20 – 23: Leg circumference at measuring point B (20 - 23 cm)

46 – 50: Leg circumference at the upper end of the hosiery (here measuring point F: 46 – 50 cm)
57 – 64: Range of length (here AF: 57 - 64 cm)

3.5.2.3 Designation of leg sizes deviating from Tables 4 and 5

The circumference ranges of the measuring points located above the ankle (according to Fig. 1) must be specified in addition to the designation according to sub-clause 3.5.2.2, as specified in sub-clause 6.5, should these deviate from the values shown in the column in Table 4, which result from the specified circumference range of the ankle (measuring point B). The same applies to the ranges of length should they deviate from the values shown in Table 5, which result from the lengths for the upper end of the hosiery.

3.6 Compressive behaviour

3.6.1 Extensibility

Hosiery must be capable of being stretched a minimum of 30% longitudinally and a minimum of 120% transversely.

Custom-made hosiery must be capable of being stretched a minimum of 80% transversely in the area of measuring points F and G.

Test according to sub-clause 4.10.

3.6.2 Practical elongation

Practical elongation must be between 15% and 120%.

For standard size hosiery, this can be a maximum of 50% of the extensibility transversely at all measuring points.

For custom-made hosiery, this can be a maximum of 70% at the measuring points F and G and a maximum of 50% of the extensibility transversely at the other measuring points.

Test according to sub-clauses 4.5.2 and 4.6.

3.6.3 Compression

For the tested measuring points, the compression can be calculated according to 4.5.2 from the stretching force during practical elongation according to sub-clause 4.8.

3.6.4 Compression classes

The hosiery must be assigned to the classes I to IV according to Table 6 depending on the compression exerted on the leg in the area of the ankle.

Hosiery exerting compression in the area of the ankle between the tolerance limits of two compression classes must be assigned to the lower class, but should be changed in manufacture to enable clear classification into one class.

3.6.5 Residual pressure ratio and pressure characteristic

The hosiery must ensure a continuous pressure reduction from the ankle to the proximal appropriate to the anatomic conditions.

The residual pressure ratios at measuring points B1, C, D, E, F and G (if applicable) can be calculated from the compression values according to sub-clause 4.9. Except for E, these must be within a range limited by the values in Table 8.

The residual pressure ratio must not be higher at any measuring point than the one below. The residual pressure ratio at measuring point E can be lower than that resulting from the interpolation of the values of D und F and can fall out of the range.

(Exception: See 4.5.4.2, Notes).

4 Test specifications

4.1 Visual inspection

As required:

Visual inspection from a reference visual distance of 0.25 m with normal vision.

Visual inspection using a magnifying glass with 6 times magnification.

Inspection using a stereoscopic microscope with 10 to 25 times magnification.

4.2 Suppliers' declaration

Declaration of the manufacturer or supplier.

4.3 Human and ecological safety

Verification, e.g. by Öko-Tex standard 100 – product class II (products with skin contact) or equivalent certificates or supplier's declaration, e.g. Öko-Tex certificates or equivalent supplier's certificates and binding declaration of the supplier and manufacturer confirming the non-use of dyeing processes or other chemical treatment.

4.4 Fibres

4.4.1 Fibre content

Test according to DIN 54 200 ff. on samples taken from the ankle area of the hosiery.

4.4.2 Identification of rubber-elastic threads

4.4.2.1 Apparatus and reagents

Microscope

Acetic acid solution, 98 % V/V in water

Formic acid solution, 85 % V/V in water

4.4.2.2 Test procedure

Three parts acetic acid solution are mixed with one part formic acid solution.

The test sample is placed on a microscopic slide, moistened with the acid solution and examined under the microscope.

If the test sample starts to swell, elastane is present. If the test sample does not change, the thread consists of elastodiene.

4.4.3 Method for measuring the thread thickness

4.4.3.1 Introduction

The method applies to natural, synthetic and textured yarns, elastane and elastodiene and serves for determination of the type of covering used, i.e. single or double.

Note: It is not possible to determine the original thickness of elastane following its treatment during covering, as variations from the original thickness can be significant.

4.4.3.2 Preparation of test samples

The test sample must be conditioned according to DIN EN 20139, sub-clause 2.2.1.

4.4.3.3 Removal of yarn from the knitted hosiery

A sample is taken from the ankle area and prepared to enable unravelling row by row. Sections each with a minimum length of 1000mm are taken from the available thread systems; sections with a minimum length of 100mm can also be used. It is to be ensured, that the yarn is not overstretched when being pulled out and that none of the filaments are damaged. The covering of the yarn must be removed carefully. The knitting construction, type of thread systems and coverings must be recorded.

Note: Distinction can not always be clearly made between the covering methods b) and e) in Table 2.

4.4.3.4 Apparatus

Instrument for measuring length, consisting of a vertical scale with millimetre division and clamps for attaching the test sample.

Cutting instrument, e.g. razor blade.

Weights for pre-tension.

Balance with an accuracy of less than 0.1 % of the test sample weight.

4.4.3.5 Procedure

4.4.3.5.1 Elastodiene

The thickness of the yarn sections removed from the covering must be determined according to ISO 2321.

4.4.3.5.2 Elastane

The yarn sections removed from the covering must be boiled for 2,0 (± 0.2) minutes in distilled water and subsequently tested as described in sub-clause 4.4.3.5.3.

The values in Table 7 are used for pre-tensioning purposes. If the yarn still curls when the pre-tension weights are applied, the pre-tension weights must be increased (to maximum 0.02 cNg/tex) until the yarn is taut.

The length of the pre-tensioned section is indicated on the scale and is limited by the clamp on the one side and the pre-tension weight on the other side.

The test sample must subsequently be cut out between both clamps and weighed with an accuracy of 0.1% of the expected weight.

4.4.3.5.3 Covered elastic yarns

The pre-tension force required for the covered elastic yarn can be determined with the aid of the linear density determined under 4.4.3.5.1 or 4.4.3.5.2. The pre-tension force is defined with 0.04 cN/tex, based on the elastic core of the yarn.

One end of the test sample must be clamped in the upper clamp and the other end loaded with a weight as specified above, rounded up to 0.05 cN g absolute.

Attachment of the weight must take place slowly and with care to avoid any sudden load being exerted on the test sample.

When attaching the weight, it is important to ensure that the section does not twist or any existing twist is retained. The loading time is 1.0 (± 0.1) minute(s).

The length of the pre-tensioned section is indicated on the scale and is limited by the clamp on the one side and the pre-tension weight on the other side.

The test sample must subsequently be cut out between both clamps and weighed with an accuracy of 0.1 % of the expected weight.

4.4.3.6 Test result

Evaluation and presentation according to ISO 1144

4.5 Pressure behaviour

4.5.1 Number of test samples

Two test samples must be used for testing each of the lengths and circumferences (double test).

4.5.2 Measurement at minimum and maximum lengths and sizes

Measurement takes place at the minimum and maximum lengths and circumferences specified by the manufacturer.

If the minimum and maximum lengths specified by the manufacturer for the position of the uppermost measuring point (D, F or G) do not deviate from each other by more than 15% (the lower value forms the basis), measurement only takes place on the basis of the mean length. If, for the uppermost measuring point other lengths than those shown in Table 5 are used, the values for the lower measuring points are accordingly interpolated.

If the minimum and maximum circumferences specified by the manufacturer for each individual measuring point should deviate from each other by maximum 10% (the lower value forms the basis), measurement takes place only according to the lower circumferences.

4.5.3 Pretreatment

4.5.3.1 Washing

Prior to testing, the hosiery must be washed once according to DIN EN 26 330/6 A. The test samples must subsequently be spun dry for two minutes and dried flat according to DIN EN 26 330, Method C.

4.5.3.2 Conditioning

The hosiery must be spread out after drying for minimum 12 hours in a standard atmosphere according to DIN EN 20139, sub-clause 2.2.1.

It must be ensured that the hosiery increases in bulk following adjustment to the standard atmosphere.

4.5.4 Determination of measuring points

4.5.4.1 Marking device

Required for the determination and marking of the measuring points is the illustrated device (2). The device consists of a base plate with base clamp in which a holding device depending on the knit type can be fixed for the foot. A length measuring device with mm graduations and measuring point markings can also be attached to base plate.

4.5.4.1.1 Circular knitted hosiery

In the case of circular knitted hosiery, the first continuous course across the heel is defined as the lower end for marking. The hosiery is fixed in the foot clamp along this course (Fig. 3, example), which in turn is fixed in the base clamp. The base clamp must be adjusted so that the course defined as a basis is located at a position of +45mm above the zero line of the length measuring device.

4.5.4.1.2 Flat bed knitted hosiery

Flat bed knitted hosiery is fixed in the base clamp by means of a foot frame (Fig. 4). The base clamp must be adjusted so that the horizontal bottom edge of the foot frame is located at a position of –25mm below the zero line of the length measuring device.

4.5.4.2 Marking test samples

After fixing the foot part in the base clamp according to sub-

clause 4.5.4.1, the hosiery is stretched in longitudinal direction so that it corresponds to the specified length and is then fixed with needles or a suitable clamp. The measuring points provided must be marked with a felt-tip pen in correspondence with the length values.

Notes:

The hosiery covers the leg up to the specified measuring point.

At the top edge, up to 5cm of the hosiery can deviate in knit (edge).

The hosiery is measured along its entire length.

For calculation of the pressure gradients, reference is made to the measured value of the clamp that is still located fully in the compression zone.

The residual pressure ratio of the upper clamp can be a maximum of 15 per cent points higher than the residual pressure ratio of the clamp below, however, not higher than the value shown in Table 8.

4.5.5 Compression measurement

4.5.5.1 Measuring principle

Measured in the force exerted by hosiery in circumferential direction, when stretched in longitudinal direction to the specified length and subsequently in transverse direction according to its size.

4.5.5.2 Test device

Testing takes place with a Hohenstein system (HOSY)[1] compression test device. The device consists of up to 20 individual, directly following tensile test devices each with a width of 5 cm. The tensioning and measuring clamps are each designed as double rollers. The hosiery is inserted between these rollers and held in the clamps by means of the inserted spiral spring sections. Each tensile test unit is driven by a stepper motor, the pulses of which provide information on the distance, i.e. the distance between both clamps of a unit. Force measurement takes place at the fixed clamp row via short-distance electronic force transducers. The complete test sequence is computer controlled.

4.5.5.3 Test sequence

The hosiery is placed in the fixed clamp row with the aid of a highly flexible spiral spring section and attached to the foot part and hosiery edge in adjustable gripping devices. The gripping devices are subsequently moved until the mark for measuring point B on the hosiery is located in the centre of clamp 2 and the end of the hosiery corresponds to the specified leg length. The second, covered spiral spring section is subsequently inserted into the hosiery and the force indicators of all measuring clamps set to zero.

The tensioning clamps are now initially raised to hosiery level, so that these can also be inserted into the lower clamp row. The clamps are subsequently moved apart until a selectable initial load is applied to each measuring clamp (= table dimension). The initial load must not exceed 5cN per cm hosiery length in the case of the compression classes I and II and 10cN in compression classes III and IV.

The computer program then calculates for each tensioning clamp the distance necessary to the given circumferences, the resultant elongation of the hosiery and the required pulse number, so that all clamps reach this position simultaneously after 20 seconds.

The hosiery is subsequently stretched six times to the leg circumference and relieved again at the same testing rate up to the table dimension.

The computer then provides a table for each clamp or measuring point, the elongation, tensional force, pressure and residual pressure ratio for the condition at the given circumferences and represents graphically the pressure characteristic along the entire leg length.

Note:

The pressure at measuring point B determines the hosiery compression class. So that this value is directly determined and not obtained by interpolation from the values of two neighbouring clamps, the hosiery must be fixed in the test device, independent of the length dimensions, so that the mark for measuring point B is located in the centre of clamp 2.

4.6 Practical elongation

The practical elongation is calculated from:

$$D_i = \frac{U_i - S_i}{S_i} \cdot 100$$

D_i = Practical elongation at measuring point i in %

U_i = Leg circumference at measuring point i in cm

S_i = Circumference of hosiery fixed in longitudinal direction with initial load applied at measuring point i (table dimension) in cm

i = Stands for measuring points B to G and for measuring clamps 1 to 20

4.7 Force

The force determined during the sixth loading cycle at the final loading point (leg circumference) is calculated on a leg covered to a height of 10mm.

$$F_i = \frac{F_s}{10}$$

F_i = Force in N/cm at measuring point i

F_s = Force in N during loading cycle at measuring point i during elongation that corresponds to practical elongation

i = Stands for measuring points B to G and for measuring clamps 1 to 20

4.8 Compression

The pressure exerted on the leg is calculated from:

$$P_i = 20\,\pi\,\frac{F_i}{U_i}$$

P_i = Compression in kPa at measuring point i

F_i = Tensional force in N/cm at measuring point i

U_i = Leg circumference in cm at measuring point i

i = Stand for measuring points B to G and for measuring clamps 1 to 20

4.9 Residual pressure ratio

The residual pressure ratio at the measuring points above B results from

$$Rd_i = \frac{P_i}{P_x} \cdot 100$$

Rd_i = Residual pressure ratio at measuring point i

1) A detailed description of the test procedure is provided in the Hohensteiner research report of January 1982 and Phlebol and Proktol: 43-41 (1982).

P_i = Compression at measuring point i in kPa

P_x = Compression at measuring point B (clamp 2)

i = Stands for measuring points B to G and for measuring clamps 1 to 20

4.10 Extensibility

4.10.1 In longitudinal direction

Test at measuring point B

The hosiery is cut in longitudinal direction and a test sample 100mm long (leg longitudinal direction) and 50 mm wide (leg circumference direction) is taken at measuring point B keeping the courses straight. The measuring point B must be located in the geometrical centre of the test sample. The longitudinal edges of the test samples progressing in test direction are trimmed with highly stretchable overlock seams.

The test is carried out as described in 4.10.2. For flat bed knitted hosiery, three stretcher pins are used, for circular knitted hosiery, only one stretcher pin is used at the measuring point level.

4.10.2 In transverse direction

Test at measuring points B, D, F and G (if applicable).

The hosiery is cut in longitudinal direction. Test samples 100mm long (leg circumference direction) and 50mm wide (leg longitudinal direction) are taken at the measuring point keeping the stitches straight. The longitudinal edges of the test samples progressing in test direction are trimmed with highly stretchable overlock seams.

The test samples are clamped with 50mm clamping length in the clamps of a tensile test machine, whereby the width of 50mm is ensured by three stretcher pins evenly distributed along the length.

The deformation rate is selected so that the load on the test samples with 5daN is reached within 30 seconds. The elongation of the test samples is documented in mm (l1).

4.10.3 Calculation of the extensibility

The extensibility E (%) is calculated as follows:

$$E = \frac{l_1 - l_0}{l_0} \cdot 100$$

with

E = Extensibility in %

l_0 = Distance in mm of measuring marks or clamps in an unloaded condition (50mm)

l_1 = Distance in mm of measuring marks or clamps after loading

5 Monitoring

5.1 Third party tests

5.1.1 Testing agencies

The Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V. keeps a list of testing agencies authorised to carry out approval and quality assurance tests.

5.1.2 Approval test

5.1.2.1 Sampling

The tests are carried out on ready to sell medical compression hosiery submitted by the manufacturer.

5.1.2.2 Scope of testing

The approval test, as a precondition for granting the right to use the quality mark, includes the scope of testing in Sections 3 and 4.

5.1.3 Quality assurance tests

5.1.3.1 Quality assurance agreement

For third party tests, the manufacturing company is obliged to conclude a quality assurance agreement, which requires the approval of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.)

5.1.3.2 Sampling

For the testing of standard size hosiery, the medical compression hosiery is taken from current production or the warehouse of the manufacturer or from distribution trade outlets.

For testing custom-made hosiery, the testing institution selects sizes randomly from about 700 available size charts and orders medical compression hosiery for these leg dimensions via distribution trade outlets or directly from the manufacturer.

In case of a justified suspicion of irregularities, the office of the appointed testing institution is instructed to carry out routine or non-routine tests.

5.1.3.3 Scope of testing

The quality assurance test includes the scope of testing in sections 3 and 4. The identity of the hosiery submitted for the approval test (prototype) must be verified.

For custom-made hosiery of articles manufactured in standard sizes and custom sizes, only the compression behaviour according to sub-clause 3.6 and marking according to section 6 are tested.

5.1.3.4 Deviations

In case of deviations from the prototype or pertinent directives, the procedure is as follows:

In case of deviations that do not affect the medical properties, the manufacturer must remedy the defects within 4 weeks and inform the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) and the appointed testing institution accordingly in writing. In case of major deviations from the prototype and/or pertinent directives, particularly deviations that affect the compression behaviour, repetitive tests must be carried out on two further medical compression hosiery (of the same size and length), which the manufacturer must make available within 4 weeks.

If the defects are not remedied, the appointed testing institution notifies the office.

5.1.4 Change to product or name

5.1.4.1 Hosiery name

If (only) the name of the quality-labelled hosiery changes or if it is marketed under a further name, the manufacturer is obliged to notify in writing the testing institution entrusted with quality assurance and the office of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.)

5.1.4.2 Product design

If changes are made to the hosiery design (e.g. type of knit,

covering and/or thickness, or linear density of yarns or coverings), this must be reported to the testing institution appointed with the quality assurance test, whereupon a quality assurance test takes place.

The change is mentioned in the quality assurance report.

The same procedure is followed if a change of name simultaneously takes place, but without an extension of the product range.

If an extension of the product range takes place due to a change to the design and product name, an approval test is necessary.

5.2 Internal quality assurance

5.2.1 Management system

The manufacturer undertakes to establish and implement a documented quality assurance management system.

5.2.2 Traceability

The manufacturer undertakes to ensure traceability in accordance with medical product law. This can take place by marking the lot on the hosiery, the pack, usage instructions, inspection tickets or in any other appropriate manner.

5.2.3 Production control

In order to meet quality requirements, tests must be carried out during production and in the event of changes to production conditions at least in accordance with sub-clauses 3.2, 3.3 and 3.6.2 to 3.6.5 (at measuring points B, B1, C, D and F or G) and documented.

6 Marking

6.1 Quality mark

Medical compression hosiery that complies with the quality conditions according to section 3, can be marked with the quality mark illustrated below.

The wording and symbols of the Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V., Düren, apply exclusively to the use of the quality mark.

6.2 Marking of hosiery

Medical compression hosiery marked with the quality mark must also show the following data:

- Manufacturer's details or number issued by the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.)
- Product name or type designation
- Compression class
- Type of hosiery and size (according to sub-clause 3.5.2.2 or 3.5.2.3) or mark "custom-made"
- Textile mark (if not shown on the pack)
- Marking for traceability (if not shown on the pack or in the usage instructions)
- Care mark (according to DIN EN 23758), date of manufacture or expiry date (if not shown on the pack or in the usage instructions).

Marking of the medical compression hosiery must be complete, permanently legible and durable.

Test according to sub-clause 4.1

6.3 Marking packaging

In addition to the marking mentioned under 6.2, the following must be shown on the pack:

- Name and address of the manufacturer or distributor
- Textile marking (if not provided on the hosiery)
- Marking for traceability (if not shown on the hosiery or in the usage instructions)
- Care mark and date of manufacture or expiry date (if not shown on the pack or in the usage instructions).

Test according to sub-clause 4.1

6.4 Usage instructions

The hosiery must be accompanied by usage instructions for the ultimate consumer, containing the following information:

- Name and address of the manufacturer or distributor
- Marking for traceability (if not shown on the hosiery or pack)
- Storage of the hosiery
- Storage life and duration of use of the hosiery
- Intended use of the hosiery
- Possible contraindications and risks
- Washing instructions if possible using washing and care symbols according to DIN EN 23 758
- Indication that skin oils, ointments, etc., can restrict the effect and durability.

Test according to sub-clause 4.1

6.5 Information for the agency concerned

The agency concerned must be provided with information on the following items in appropriate form:

- Ranges of length and circumference of standard size hosiery if these deviate according to sub-clause 3.5.2.3 from the respective columns in Tables 4 and 5.
- Proper storage
- Storage life

6.6 Alterations

In order to be effective any alterations to these Quality and Test Specifications, even if these are only changes of editorial nature, require the prior written approval by RAL German Institut for Quality Assurance and Certification, reg. assoc..

They will be put into force by notification of the Board of the Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e. V. (Quality Assurance Association Medical Compression Hosiery, reg. assoc.) to the quality mark holders.

Table 1: Thread thickness

Hosiery type according to sub-clause	Material	Knitting thread		Weft thread
		Minimum thickness core[1)]	Minimum thickness of total knitting thread	Minimum thickness core[1)]
3.2.1.1.	Elastodiene	No. 125/140	No. 110/120	No. 70/80
3.2.1.2.	Elastodiene	No. 125/140	No. 110/120	No. 80/90
3.2.1.1.	Elastane	44 dtex	180 dtex	390 dtex
3.2.1.2.	Elastane	44 dtex	180 dtex	310 dtex

1) After removal of covering

Because the specified minimum thicknesses are not reached due to permanent elongation, up to 15% is tolerated for elastane and up to 10% for elastodiene.

Table 2: Types of covering

a) Double covering: Wrapping minimum two spirals of non-elastic threads in opposite directions around an elastic core

b) Single covering: Wrapping minimum of spiral of non-elastic thread around an elastic core

c) Stitch covering: Knitting a chain stitch of minimum one non-elastic yarn around an elastic core

d) Core spinning: Spinning staple fibres around an elastic core

e) Core twisting: Twisting together a non-elastic yarn with elastic yarn

f) Air jet covering: Covering an elastic core with a non-elastic yarn

Table 3: Types of hosiery

Hosiery type	Code
Below-knee hosiery	AD
Mid-thigh hosiery	AF
Thigh hosiery	AG
Panty hosiery	AT

Table 4: Leg circumferences and sizes

Leg circumferences and size																											
Circum-ference code	Slender supplement					Sizes*													Sturdy supplement							
						18	19	20	21	22	23	24	25	26	27	28	29	30								
Circumferences in cm																											
cG	43	45	46	48	49	51	52	54	55	57	58	60	61	63	64	66	67	69	70	72	73	74	76	77	79	80
cF	35	37	38	40	41	43	44	46	47	49	50	52	53	55	56	58	59	60	61	62	63	65	66	68	69	71
cE	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	–
cD	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	49	–	–
cC	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	–	–	–
cB1	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	–	–	–	–
cB	–	–	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	–	–	–	–	–
cA	–	–	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	–	–	–	–	–
cY	–	–	–	–	–	–	28	29	30	31	32	33	34	35	36	37	38	–	–	–	–	–	–	–	–	–
*) correspond to circumferences cB																											

Table 5: Leg lengths

Length code	Leg length in cm						
IG	65	68	71	74	77	80	83
IF	54	57	59	62	64	67	69
IE	41	43	45	47	49	51	53
ID	35	37	38	40	41	43	44
IC	27	29	30	32	33	35	36
IB_1	19	20	21	22	23	24	25
IB	10	11	11	12	12	13	13

Table 6: Compression classes

Compression class	Compression intensity	Compression in kPa[1)]	Compression in mmHg[2)]
I	Low	2.4 to 2.8	18 to 21
II	Moderate	3.1 to 4.3	23 to 32
III	High	4.5 to 6.1	34 to 46
IV	Very high	6.5 and higher	49 and higher
[1)] 1 kPa = 7.5 mmHg [2)] 1 mmHg = 0.133 kPa			

Table 7: Pre-tension weights

Yarn	Pre-tension weight in cN/tex
Elastane	0.01 ± 0.0025
Covered elastic yarns	0.04 ± 0.005
Synthetic yarn and non-texturized yarns	0.5 ± 0.1
Texturized threads	2.0 ± 0.2

Table 8: Residual pressure ratio

Compression class	Residual pressure ratio in % of pressure at the ankle		
	at measuring point B1	at measuring point C	at measuring point F or G
I	70 to 100	50 to 80	20 to 60
II	70 to 100	50 to 80	20 to 50
III	70 to 100	50 to 70	20 to 40
IV	70 to 100	50 to 70	20 to 40

Table 9: Test plan (for all compression classes)

Type of test	Approval test				Quality assurance			
	Only standard sizes	Standard and custom		Only standard size production	Only standard sizes	Standard and custom		Only custom-made production
		Standard	Custom			Standard	Custom	

Time of test		On application				Minimum yearly			
Type of hosiery		Longest type of hosiery offered[1](according to Table 3)				According to selection of appointement testing institution			
Number of sizes/lengths (pair or tights)		2 each of all sizes and length	2 each of all sizes and length	2[3]	6[3]	2 each in 2 sizes[2], in all length	2 each in 2 sizes[2], in all length	1[3]	2[3]
Scope of test	Compression test [4]	All sizes and length	All sizes and length	2 pairs	6 pairs	2 pairs	2 pairs	1 pair	1 pair
	Other tests[5]	4 legs	2 legs	2 legs	4 legs	2 legs	1 leg	1 leg	1 leg

1) AT or AG as selected by the appointed testing institution
2) Selection of sizes/lengths based on the presented size chart by the appointed testing institution
3) According to sizes specified by the appointed testing institution
4) According to sub-clauses 3.6.2 to 3.6.5
5) According to sub-clauses 3.1, 3.2, 3.3, 3.4, 3.5, 3.6.1
sizes according to sub-clause 6.5 if required

Fig. 1: Measuring points, leg lengths and circumferences

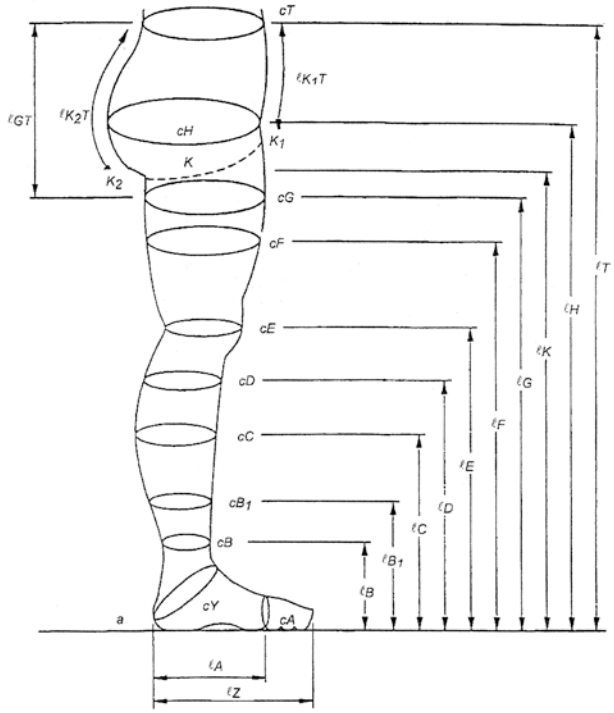
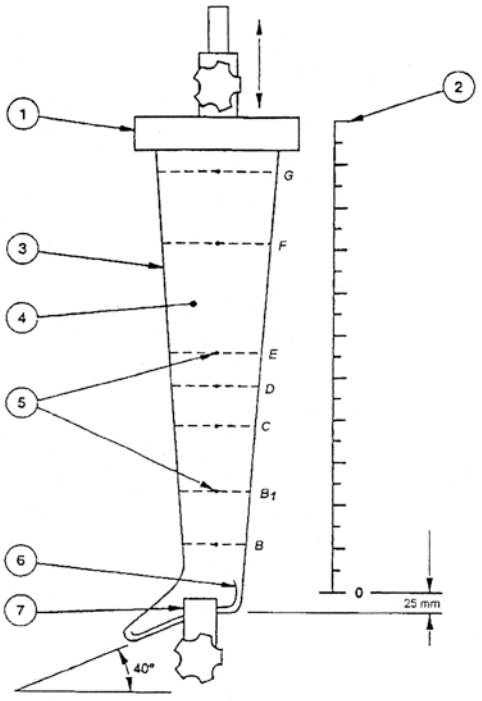


Fig. 2: Measuring point marking device

Example of flat bed knitted hosiery



1 Fixing device (clamps or needles)

2 Rule

3 Hosiery

4 Base board

5 Measuring points

6 Foot frame

7 Base clamp

Fig. 3: Foot clamp for circular knitted hosiery[2]

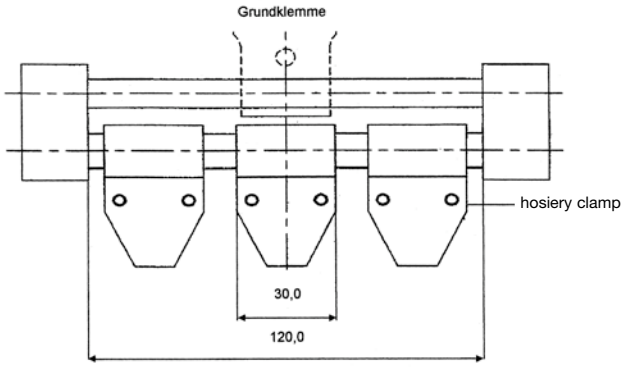
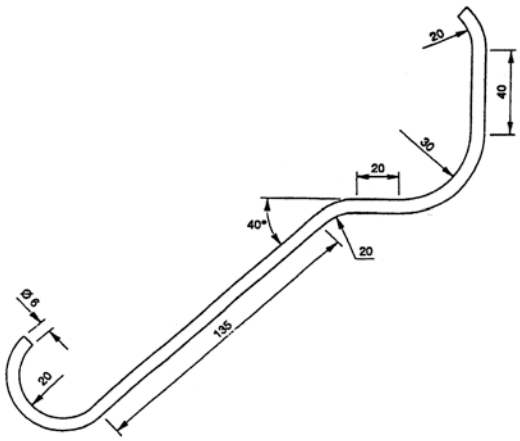


Fig. 4: Foot frame for flat bed knitted hosiery



2) verification of source by Gütezeichengemeinschaft

Implementation Guidelines for the Award and Use of the Quality Mark for Medical Compression Hosiery

1 Quality criteria

The quality criteria testified by the Quality Mark comprise the Quality and Testing Guidelines for Medical Compression Hosiery. These are supplemented and updated in line with technical advances.

2 Award

2.1 The Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V. (Quality Mark Association for Medical Compression Hosiery) grants manufacturers the right to use the quality mark for medical compression hosiery on application.

2.2 Applications shall be made in writing to the office of the Gütezeichengemeinschaft, August-Klotz-Straße 16 d, D-52349 Düren, enclosing a Declaration of Acceptance bearing a legally binding signature for the applicant (Sample 1) and a production sample.

2.3 The technical commission examines the application and the preconditions for granting the mark. On their behalf – at the request of the applicant – a testing institution authorised by the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) tests the products of the applicant. Testing is performed in accordance with the quality and testing guidelines. The expert of the institute appointed with testing, inspects the applicants premises and determines whether the technical preconditions for the manufacture of medical compression hosiery are met in accordance with the quality mark. He is entitled to take materials and further test samples and examine the documents serving for quality assurance. All information obtained shall be treated in the strictest confidence. The testing institution prepares test reports on inspection of the premises and product tests, which are sent to the applicant and the technical commission. The appointed inspector shall present his credentials before commencement of testing. All costs of testing are borne by the applicant.

2.4 If the products pass, the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) executive, acting at the suggestion of the technical commission awards the quality mark to the applicant. An award certificate is issued (sample 2). If the products fails, the technical commission rejects the application, giving its reasons in a letter of rejection.

2.5 The award of the quality mark can be restricted to individual company units, specific product groups or particular products. At the same time as granting the quality mark, the user of the mark is allocated a manufacturer's number.

2.6 The Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) publishes the user entitled to use the mark in a list, which is made known to the members, which can however also be passed on to authorities and other interested parties.

3 Use

3.1 Quality mark users may use the quality mark for medical compression hosiery solely for products complying with the Quality and Testing Guidelines.

3.2 The Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) has the sole and exclusive right to commission the manufacture of means of printing the quality mark (metal stamps, embossing stamps, printing plates, lead seals, seal stamps, rubber stamps, etc), to issue them or have them issued to quality mark users, and to make stipulations as to their use. Quality mark users may only use means of printing issued by the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.). Modifications or unauthorised editions are inadmissible. The quality mark user may not use any other marks that could be confused with the quality mark.

3.3 The executive may make special stipulations for the use of the quality mark of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) in product promotion and in promotion of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) in order to safeguard fair competition and to prevent misuse. Such stipulations shall not hinder individual promotion, which is subject to the same principles of fair competition.

3.4 Quality mark users are free to mark in their own publications (brochures, catalogues, quotations, delivery notes, letters, etc.), medical compression hosiery for which the right to use the quality mark has been granted and this applies similarly to their packaging.

3.5 In the event that the right to use the quality mark is withdrawn, the award certificate and all quality mark printing articles shall be surrendered without reimbursement; likewise in the event that the right to use the quality mark lapses by other means.

4 Monitoring

4.1 The Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) is entitled and obliged to monitor the use of the quality mark and compliance with the Quality and Testing Guidelines. Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) shall be furnished with documentary proof of continuous monitoring by way of a monitoring agreement between the respective quality mark user and a neutral testing institution authorised by the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.).

4.2 Responsibility for ensuring compliance with the Quality and Testing Guidelines lies entirely with the quality mark users themselves. Users are placed under a duty to perform continuous quality control. All factory controls must be conscientiously recorded. Quality mark users shall submit their quality-labelled products to monitoring in accordance with the quality assurance contract and associated requirements of the Quality and Testing Guidelines. The Technical Commission can perform additional tests and inspections of premises through an authorised testing institution at any time. This applies in particular to negative results of regular product tests or complaints. Samples requested for testing purposes must be provided immediately. Products of the quality mark user can also be taken from distribution trade outlets and tested. Such sam-

ples must be clearly marked immediately. Sealed control samples must be sent to the manufacturer concerned. The costs shall be borne by the quality mark user. The test must not be delayed by the obligation of the inspector to prove his identity prior to commencement of the test.

The Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) is obliged to verify the continuity of monitoring of the quality mark user to the RAL.

4.3 In the event that the testing institution discovers noncompliance with the quality and testing guidelines at the quality mark user, the technical commission of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) shall order retesting. The technical commission shall also determine the type, extent and time of retesting.

If the retesting is also not passed, the test as a whole is failed by the testing institution. The costs for retesting shall be borne by the quality mark user. The further procedure subsequently depends on the implementation guidelines for the award and use of the quality mark.

4.4 The appointed testing institution shall issue a test report for each test result. The Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) and the quality mark user shall each receive a copy. The office of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) shall treat all test results in the strictest confidence.

4.5 In the event of unjustified complaint, the costs of inspection and testing shall be borne by the complainant; in the event of a justified complaint, the costs shall be borne by the quality mark user.

5 Measures in the event of noncompliance

5.1 Noncompliance exists if the quality mark user fails to comply with the Quality and Testing Guidelines or other contractual agreements regulating the use of the quality mark.

5.2 If the technical commission notices noncompliance, it shall propose measures to the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) executive. According to the severity of the noncompliance, the available measures are as follows:

a) Caution

b) Increased monitoring tests

c) Warning

d) Payment of a contractual penalty up to € 12,500.— depending on the extent of fault

e) Temporary or indefinite withdrawal of the right to use the quality mark

f) Exclusion from the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.)

5.3 The measures stipulated in section 5.1 may be imposed in combination.

5.4 Quality mark users who are guilty of repeated or serious noncompliance will lose their right to use the quality mark for a temporary or indefinite period. This applies similarly to quality mark users who delay or hinder testing.

5.5 The affected party shall be given a hearing before any measures are imposed.

5.6 Imposed measures enter into force on the date they become legally effective.

5.7 In urgent cases, the director of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) may provisionally withdraw the right to use the quality mark with immediate effect. Such withdrawal must be confirmed or cancelled by the technical commission of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) executive within 14 days.

6 Appeal

6.1 Quality mark users may appeal in writing against imposed measures within four weeks to the director, who shall decide on the appeal in consultation with the technical commission and executive.

6.2 If the executive rejects an appeal, the appellant may apply to a tribunal for arbitration within four weeks of notification in accordance with § 12 of the articles of the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.)

6.3 Measures taken by the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) to protect the quality mark in accordance with these implementing guidelines shall not affect the rights of quality mark users, any claims for damages attributed to noncompliance of the quality mark user shall also be asserted under civil law.

7 Reaward

If the right to use the quality mark has been withdrawn without a time limit, then it cannot be reawarded before expiry of at least 12 months after withdrawal. The procedure is as stipulated in section 2. The Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) executive may impose supplementary requirements.

8 Changes

These implementation guidelines and the samples they contain (Declaration of Acceptance, Award) are approved by RAL. Modifications to these Quality and Testing Guidelines, including editorial changes, require prior written consent from RAL. Any such modifications shall enter into force a reasonable period after their announcement by the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) executive.

Declaration of Acceptance

1 The undersigned applies herewith to the Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V. (Quality Mark Association for Medical Compression Hosiery) for:

- membership*,
- award of the right to show the Quality Mark for "Medical Compression Hosiery"*.

2 The undersigned has read and understood, and acknowledges and accepts as binding:

- the Quality and Testing Guidelines for Medical Compression Hosiery
- the Articles of the Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.,
- the Articles Governing Use of the Quality Mark
- the Implementation Guidelines including samples 1 and 2

(place, date)

(stamp and binding signature)

*Delete as appropriate

Award

The Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.
(Quality Mark Association for Medical Compression Hosiery)
hereby awards
in accordance with the test report submitted to the Quality Committee

_____
(Company)

as recognised by the RAL Institute for Quality Assurance and Certification
(RAL Deutsches Institut für Gütesicherung und Kennzeichnung e.V.)
and registered as a collective trademark at the German Patent Office

"Quality Mark for Medical Compression Hosiery"
according to the following mark

The Quality Mark must be used in conjunction
with the isued No. _____ herewith.

_____ , _____
(Place) (Date)

Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.
Quality Mark for Medical Compression Hosiery

_____ _____
Chairman Managing Director

History

The "Reichsausschuss für Lieferbedingungen" (RAL) - Committee of the German Reich for Terms and Conditions of Sale - was founded in 1925 as a combined initiative of the German private sector and the German government of that time. The joint aim was the standardization and clear definition of precise technical terms of delivery. For this purpose, fixed quality standards and their control were needed - the system of quality assurance was born. Its implementation required the creation of an independent and neutral institution as a self-governing body of all parties active in the market. That was the moment of birth for RAL and ever since that time it has been the competent authority for the creation of quality labels.

RAL Today

RAL acts as an independent service provider in its fields of activity. It is recognized as a non-profit organization and organized in the legal form of a registered association. Its organs are Executive Committee, Board of Trustees, General Assembly of Members and the management.

RAL's independent and neutral position finds expression in the fact that the principles of its activities are established by the Board of Trustees which is composed of representatives from the leading organizations representing industry, consumers, agriculture, the federal ministries and other federal bodies. They have a permanent seat and vote on that body. In addition to them, the General Assembly of Members elects four quality assurance associations on the Board of Trustees as representatives of the RAL members.

RAL's Areas of Competence

- RAL creates quality labels
- RAL provides internationally binding colour charts
- RAL awards the Blue Angel eco-label and the European eco-label
- RAL is responsible for registrations, agreements and RAL certificates

RAL DEUTSCHES INSTITUT FÜR GÜTESICHERUNG UND KENNZEICHNUNG E.V.
(RAL GERMAN INSTITUTE FOR QUALITY ASSURANCE AND CERTIFICATION)

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