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Medical Compression Armsleeves

Quality Assurance
RAL-GZ 387/2

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Compression Armsleeves

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These quality and test specifications have been prepared by RAL Deutsches Institut für Gütesicherung und Kennzeichnung e.V. (RAL German Institute for Quality Assurance and Labelling) based on the principles for quality marks as part of an approval procedure with the co-operation of the Federal Ministry of Germany together with the professional and organisational bodies and authorities concerned.

Sankt Augustin, January 2008

RAL DEUTSCHES INSTITUT
FÜR GÜTESICHERUNG
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Quality and test specifications for medical compression armsleeves

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They will be supplemented and updated in line with technical advances and industry standards.

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All the terms and definitions in the quality and test specifications for medical compression hosiery apply accordingly for medical compression armsleeves.

2.1 Extensibility

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2.19 Starting measuring point for compression armsleeves

The starting point for measuring the pressure is the area at the distal end of the compression armsleeve, but not more than 6 cm up the arm. All the requirements referring to measuring point B as the basic value, must be applied accordingly for compression armsleeves.

3 Requirements

All the requirements defined in the quality and test specifications for medical compression stockings also apply accordingly for medical compression armsleeves. Definitions, which deviate from, or are complementary to these quality requirements, are laid down as follows:

3.2.2 Design

Compression armsleeves have no heel and no toes.

3.4 Armsleeve types

The different types of armsleeve are primarily manufactured according to Table 3, and the type that is ultimately selected depends on the areas of the arm to be treated. The designations are based on the measuring points defined in Fig. 1. Other types of armsleeve are possible.

3.5 Armsleeve sizes

The specifications for leg circumferences and lengths apply accordingly for arm circumferences and lengths.

3.5.1 Custom-made armsleeves

Manufacture takes place individually according to the circumference and length of the patient's arm.

3.5.2 Standard size armsleeves

The manufacture is carried out in standard sizes, which are characterised by the arm circumferences and arm lengths at the specified measuring points laid down in Fig. 1 of this supplementary issue.

3.5.2.1 Armsleeve sizes and lengths

These are based on the arm size combinations provided by the respective manufacturer.

3.5.2.2 Designating the armsleeve type and the armsleeve size

The type code consists of an alphabetic key for the type of armsleeve (see Table 3 in this supplementary issue) followed by three paired values. These indicate the arm sizes for which the armsleeve is intended:

a) Circumference range at the wrist (measuring point C)

b) Circumference range at the end of the armsleeve (measuring point F or G)

c) Length range (in terms of the overall length of the respective type of armsleeve)

The code is designated analogously to the requirements for medical compression stockings.

There is no generally applicable basic table for armsleeves. For this reason, all the circumference ranges at all measuring points must be declared in addition to the code in compliance with section 6.5 of the quality and test specifications. This also applies to the lengths.

3.6 Compressive behaviour

3.6.4 Compression classes

The armsleeves are assigned to classes 1-3 as shown in Table 6 depending on the compression exerted on the starting measuring point on the arm.

Armsleeves exerting compression at the starting measuring point between the tolerance limits of two compression classes, must be assigned to the lower class, but should be sufficiently changed in manufacture to enable clear classification into one class.

3.6.5 Residual pressure ratio and pressure characteristic

The armsleeve must apply a continuous pressure reduction from the wrist in a proximal direction, that is appropriate to the anatomic conditions.

The residual pressure ratios at measuring points D, E, F and G (if applicable) are calculated according to section 4.9 of the quality and test specifications for medical compression stockings. However, in the case of armsleeves, the calculations are based on the value at the starting measuring point. With the exception of E, they must lie within a range whose limits are set by the values of these quality and test specifications given in Table 8.

The residual pressure ratio must not be higher at any measuring point than the one below. In particular, the residual pressure ratio at measuring point E must not be higher than that at measuring point D.

4 Test specifications

4.1 Visual inspection

Visual inspection is carried out as required.

Visual inspection is carried out from a reference visual distance of 0.25 m with normal vision using a magnifying glass with 6 times magnification.

The stereomicroscopic inspection is carried out at a 10 to 25 fold magnification.

4.2 Suppliers' declaration

The manufacturer or upstream supplier must have submitted a declaration.

4.3 Human and ecological safety

Verification of the human ecological safety of the product is established, 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 upstream supplier's certificates and binding declaration of the manufacturer confirming the non-use of dyeing processes or other chemical treatment.

4.4 Fibres

4.4.1 Fibre content of the armsleeve

The fibre content of the armsleeve is tested according to DIN 54 200 ff. on samples taken from the armsleeve at the location of the starting measuring point.

4.4.2 Identification of rubber-elastic threads

4.4.2.1 Test apparatus and reagents

The following test apparatus and reagents must be at hand:

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 is used for the 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 the procedure can cause significant changes to the original thickness.

4.4.3.2 Pretreatment of test samples

The sample is conditioned according to DIN EN ISO 139, section 3.1.

4.4.3.3 Removal of yarn from the knitted hosiery

A sample is taken from the starting measuring point and prepared so that it is possible to unravel it row by row. In each case, segments with a minimum length of 1000mm are taken from the available thread systems. Sections with a minimum length of 100mm can also be used. Here 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 is removed carefully and the knitting construction, type of thread systems and coverings recorded.

Note:

A distinction cannot always be clearly made between the covering methods b) and e) in Table 2.

4.4.3.4 Test apparatus

The following test apparatus is used:

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 Test 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 section 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 g/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 pretension weight on the other side.

The test sample is subsequently 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 yarn count 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 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 pretension 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 results

Evaluation and presentation of the test results 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 quality mark user.

If the minimum and maximum lengths specified by the quality mark user for the position of the uppermost measuring point (F or G) do not deviate from each other by more than 15% (the lower value forms the basis here), measurement only takes place on the basis of the mean length.

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

4.5.3 Pretreatment

4.5.3.1 Washing

Prior to testing, the armsleeves must first be washed once according to DIN EN ISO 6330/7A. The test samples must subsequently be spun dry for two minutes and dried flat according to DIN EN ISO 6330, Method C.

4.5.3.2 Conditioning

The hosiery must be spread out after drying for a minimum of 12 hours in a standard atmosphere according to DIN EN ISO 139, section 3.1.

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

A device is required for the determination and marking of the measuring points. The device consists of a base plate with base clamp in which a holding device can be fixed. A length measuring device with mm graduations and measuring point markings can also be attached to the base plate.

4.5.4.2 Marking test samples

After fixing the lower end of the armsleeve in the base clamp according to sub clause 4.5.4.1, the armsleeve is stretched in a 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 specifications.

Notes:

The armsleeve covers the arm up to the specified measuring point.

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

The armsleeve 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 10 percent 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

The force exerted by hosiery in a circumferential direction when stretched in a longitudinal direction to the specified length and subsequently in a transverse direction corresponding to its size, is measured.

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 tensile test devices, each with a width of 5 cm and positioned directly following one another. 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 armsleeve is placed in the fixed clamp row with the aid of a highly flexible spiral spring section and the upper and lower armsleeve edges are attached to adjustable gripping devices. The gripping devices are subsequently moved until the mark on the armsleeve indicating the starting measuring point, is located in the centre of a clamp and the distance from this to the end of the armsleeve corresponds to the specified arm length. The second, covered spiral spring section is subsequently inserted into the armsleeve and the force indicators of all measuring clamps set to zero.

The tensioning clamps are now initially raised to the armsleeve level, so that these can also be inserted into the lower clamp row. The clamps are subsequently moved apart until a defined initial load is applied to each measuring clamp (= table dimension).

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

The armsleeve is subsequently stretched six times to the arm circumference and, at the same testing rate, relieved again to the table dimension.

The computer then provides a table for each clamp or measuring point, giving 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 length of the arm.

Note:

The pressure at the starting measuring point determines the armsleeve compression class. So that this value is directly determined and not obtained by interpolation from the values of two neighbouring clamps, the armsleeve, irrespective of its length dimensions, must always be fixed in the test device in such a way that the mark for this measuring point is located in the centre of clamp.

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. The Hohenstein system (HOSY) is an internationally acknowledged and established test procedure. No equally valuable test procedures are available.

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 = Arm circumference in cm at the measuring point

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

i = measuring points C to G and measuring clamps 1 to 20.

4.7 Force

The force determined during the sixth loading cycle at the final loading point (arm circumference) is calculated on an arm 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 stretching

i = measuring points C to G and measuring clamps 1 to 20.

4.8 Compression

The pressure exerted on the arm 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 = Arm circumference at measuring point i in cm

i = measuring points C to G and measuring clamps 1 to 20.

4.9 Residual pressure ratio

The residual pressure ratio at the measuring points above the starting measuring point results from

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

Rd_i = Residual pressure ratio at measuring point i

P_i = Compression in kPa at measuring point i

P_x = Compression at the starting measuring point

i = measuring points C to G and measuring clamps 1 to 20.

4.10 Extensibility

4.10.1 In longitudinal direction

Test at starting measuring point

The armsleeve is cut open in the longitudinal direction and a test sample 100 mm long (arm longitudinal direction) and 50 mm wide (arm circumference direction) is taken, thereby keeping the courses straight. The measuring point above the wrist 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 armsleeves, three stretcher pins are used, for circular knitted armsleeves, only one stretcher pin is used at the measuring point level.

4.10.2 In transverse direction

Test at the starting measuring point and measuring points For G (where applicable).

The armsleeve is cut open in the longitudinal direction. Test samples 100 mm long (arm circumference direction) and 50 mm wide (arm longitudinal direction) are taken at the measuring points to be tested, thereby 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 50 mm clamping length in the clamps of a tensile test machine, whereby the width of 50 mm is ensured by three stretcher pins evenly distributed along the length.

The deformation rate is defined so that the load on the test samples of 5 daN, is reached within 30 seconds The elongation of the test samples is documented in mm (l_1).

4.10.3 Calculation of the extensibility

The extensibility E (%) is calculated as follows:

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

with

E = Extensibility in %

l_o = 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 Quality Mark Association for Medical Compression Hosiery (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 armsleeves 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 quality mark user is obliged to conclude a quality assurance agreement with the testing agency, 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 armsleeves, the medical compression armsleeves are taken from the current production or from the warehouse of the manufacturer or from the distribution trade outlets.

For testing custom-made armsleeves, the appointed testing institution selects dimensions and orders medical compression armsleeves for these arm dimensions via distribution trade outlets or directly from the quality mark user.

In case of a justified suspicion of irregularities, the office of the Quality Mark Association instructs the appointed testing institution to carry out scheduled or unscheduled 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 armsleeves submitted for the approval test (model) must be verified.

5.1.3.4 Deviations

In case of deviations from the model 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 of the completion of this accordingly in writing. In case of major deviations from the model and/or pertinent directives, particularly deviations that affect the compression behaviour, repetitive tests must be carried out on two further medical compression armsleeves (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 of the Quality Mark Association.

If irregularities are confirmed for the quality mark user, the Quality Mark Association is empowered to take further measures in accordance with the implementation guidelines.

5.1.4 Changes to product or name

5.1.4.1 Armsleeve name

If (only) the name of the quality-labelled armsleeve changes or if it is marketed under a further name, the quality mark user is obliged to notify in writing the testing institution entrusted with quality assurance and the office of the Quality Mark Association.

5.1.4.2 Product design

If changes are made to the armsleeve 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 to carry out the quality assurance testing. A quality assurance test will then take place.

A passage referring to the change is added 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 in the design and product name, an approval test is necessary.

5.2 Internal quality assurance

All the provisions in the quality and test specifications for medical compression hosiery apply accordingly for medical compression armsleeves.

6 Marking

All the provisions in the quality and test specifications for medical compression stockings apply accordingly.

7 Changes

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.).

Tables

Table 1

The provisions in the quality and test specifications for medical compression stockings apply.

Table 2

The provisions in the quality and test specifications for medical compression stockings apply.

Table 3

Armsleeve type	Alphabetic key
Armsleeve	CF or CG
Armsleeve with shoulder	CH

Table 4 and Table 5

The parameters in Table 4 and Table 5 of the quality and test specifications for medical compression stockings do not apply for these quality assurance specifications.

Table 6

Compression class	Compression intensity	Compression in kPa	Compression in mmHg
1	Mild	2.0 to 2.8	15 to 21
2	Moderate	3.1 to 4.3	23 to 32
3	Strong	4.5 to 6.1	34 to 46

Table 7

The provisions in the quality and test specifications for medical compression stockings apply.

Table 8

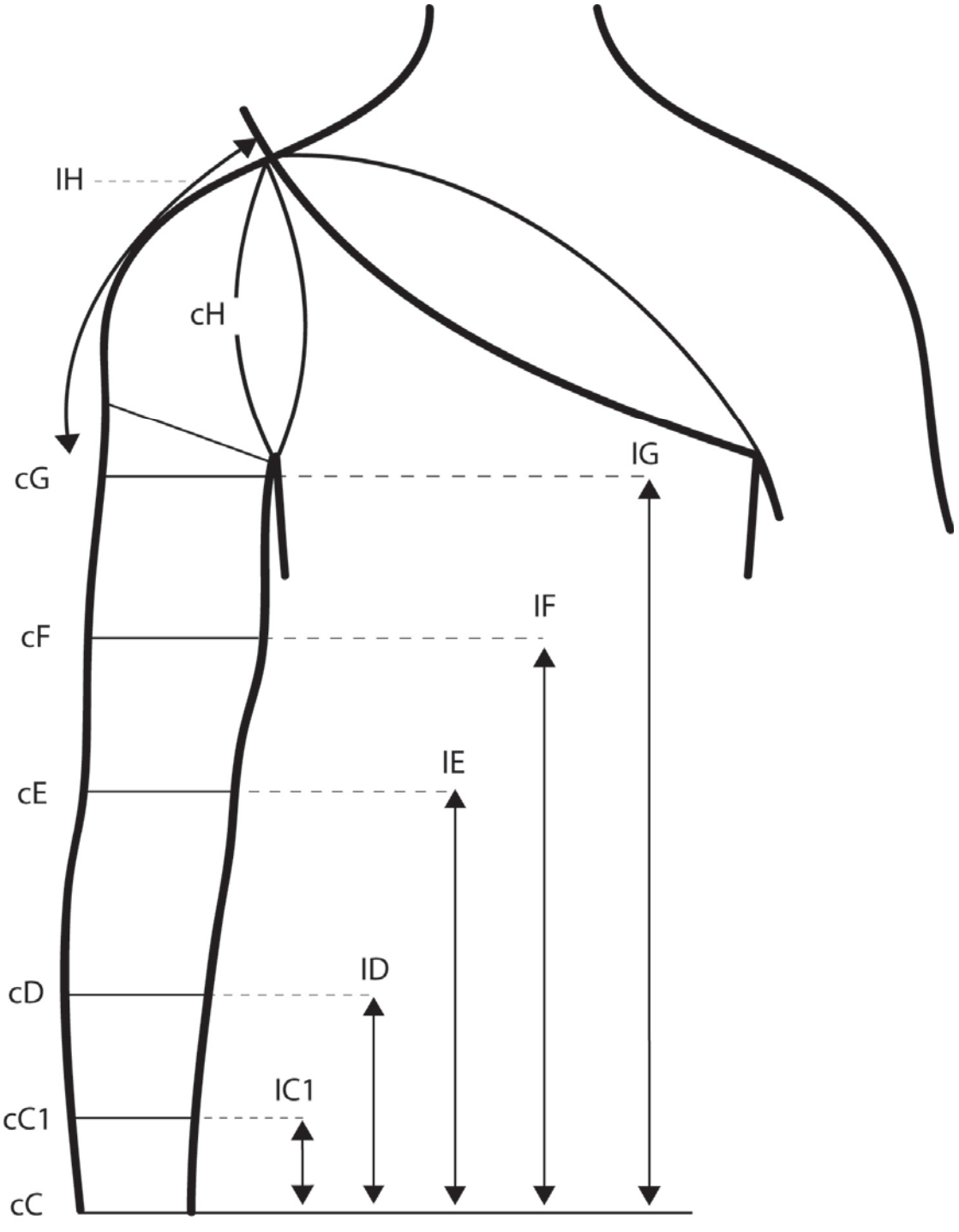
Residual pressure ratio in % of the pressure at measuring point C1	
At measuring point D	At measuring point F or G
60 to 100	40 to 90

Table 9: Test plan (for each article and compression class)

Type of test		Approval test				Quality test			
		Only standard sizes	Standard and custom		Only custom-made	Only standard sizes	Standard and custom		Only custom-made
			Standard	Custom			Standard	Custom	
Time of test		**On application**				**At least once annually**			
Type of hosiery		Longest type of armsleeve on offer [1]				According to selection of appointed testing institution			
Number of sizes/lengths to be submitted (units or armsleeves		4 of each in 2 sizes and lengths[6][7]	4 of each in 2 sizes and lengths[6][7]	4[3]	8[3]	4 in 1 size and 1 length [2][7]	4 in 1 size and 1 length [2][7]	2[3]	2[3]
Scope of test	**Compression test [4]**	All sizes and lengths submitted	All sizes and lengths submitted	4	8	2	2	2	2
	other tests [5]	2	1	1	2	2	1	1	1

1) CG, if available with topband
2) Choice of size and length by the appointed test agency from the submitted size chart. The selected size and length is different every year.
3) according to the measurement data specified by the appointed test agency
4) in accordance with sections 3.6.2 to 3.6.5 RAL-GZ 387/1, January 2008
5) in accordance with sections 3.1, 3.2, 3.3, 3.4, 3.5, 3.6.1 RAL-GZ 387/1 January 2008
6) 4 armsleeves in 2 sizes (if only 1 length manufactured) or 4 armsleeves in 2 sizes (if different lengths are manufactured)
7) Extra sizes and different topband widths must be considered as separate sizes, which must be tested for compression separately

Figure 1



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.

2.2 Applications shall be made in writing to the office of the Gütezeichengemeinschaft, August-Klotz-Straße 16 d, 52349 Düren, Germany 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 fulfilment of the preconditions for granting the mark. On their behalf and based on the applicant's own choice, 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 applicant's 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 relating to the 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 test, the Quality Mark Association for Medical Compression Hosiery (Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe e.V.) executive, acting on the recommendation of the technical commission, awards the quality mark to the applicant. An award certificate is issued (sample 2). If the products fail the test, 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.) announces the name of the user entitled to use the mark by adding it to a list, which is made known to the members. This list 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 media allowing the printing or reproduction of 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 the media for printing or reproduction that have been 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 In their own publications (brochures, catalogues, quotations, delivery notes, letters, etc.), quality mark users are free to identify those 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. The 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 Every quality mark user must ensure his/her own compliance with the Quality and Testing Guidelines. Users are under obligation to perform continuous quality control. All factory controls must be conscientiously recorded. Quality mark users shall submit their quality-labelled products for 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 in cases where there have been negative results in the regular product tests or where there are 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 samples 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 date 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,- EURO 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 implementation guidelines, shall not affect the rights of quality mark users to claim, if need be under civil law, for damages directly attributable to infringements or irregularities.

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 Armsleeves
- 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

GÜTEZEICHEN
MEDIZINISCHE
KOMPRESSIONS-
STRÜMPFE
RAL

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

_____, _____

(Place) (Date)

Gütezeichengemeinschaft Medizinische Kompressionsstrümpfe

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 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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