

KBOH-TNO Homologation Directive D 01

AIDS FOR SHOWERING, SHOWERING IN A SITTING POSITION

This report is a reissue of the KBO-TNO Homologation Directive D 01 of May 1995. Apart from the changes from KBO to KBOH as being responsible for the certification for the GQ-approval mark, no changes in requirements and/or definitions and measuring procedures are made. A checklist for the Medical Devices is added.

In case of doubt the Dutch text is definite

KBOH, Quality and Usability Research of Technical Aids

Woerden, November 1997

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1 Introduction

1.1 The KBOH-TNO approval mark GQ

The KBOH-TNO approval mark symbolises Guaranteed Quality in a stylised G and Q. The approval mark provides security to the users of technical facilities. Aids provided with the approval mark comply with clarity defined requirements as regards functionality, reliability and durability. This is achieved by means of random tests carried out to verify whether a technical aid still meets the requirements.

1.2 Shower aids for showering in a sitting position

These shower aids are designed for people not able to use a bathroom safely or when standing for a long time. There are non-moveable shower aids (fixed position or moveable within the bathroom) and moveable aids enabling the user to effect a limited number of transfers for using the bathroom facilities. Users of these shower aids may use the bathroom independently or be fully dependent on the attendant for the daily routine activities. This wide range of users' needs compared to the users' functional limitations and possibilities, have resulted in a description of 18 different clusters for shower aids.

This homologation directive D 01 outlines the requirements, measuring procedures and administrative regulations applicable to the test of shower aids.

1.3 Area of application

In the field of aids for showering a wide range of models is offered on the market. For the time being, this homologation directive is limited to shower aids for showering in a sitting position.

There are aids offering support when assuming a sitting posture when performing hygienic activities (under a shower or at the sink) and possibly toilet use. These aids may be suitable for fixing to the wall or on the floor (usually called shower seats), moveable (shower stools and chairs) or moveable by rolling (shower wheelchair, push chair/self-propelled). Aids designed for hygienic activities with users in a supine position (shower stretchers, shower frames and shower cars) are not included in this homologation directive.

Aids specifically designed for toilet use (commodes and elevated toilet seats) are not included in this instruction either.

Support aids specifically designed for placing in a bath are also excluded.

In addition, the following restrictions have been taken into account:

- Products for children are only submitted to a test if they are suitable for loads exceeding 75 kg.
- As regard to fixedly placed products the armrests/side rests are only included in the test if they (can) form a direct part of the construction of sitting support components. Armrests fixed separately to a wall or the floor are not included in the products to be tested.

The tests of the product group will be performed by the TNO Road Vehicles Research Institute (hereafter referred to as TNO).

1.4 Homologation directive

The homologation directive has been compiled in close co-operation between KBOH, P₅ rca and TNO.

Chapter 6 deals with the requirements relating to the functional and technical aspects including assessments of the suitability for sitting and performing activities, making transfers, moving and use in the bathroom (area of application and assessments of strength, durability, safety and maintenance). The contents of this chapter is, after consultation with and permission of KBOH, entirely based on the GMD-publication 'Shower aids for showering in a sitting position, target groups, requirements and evaluation criteria'. As much use as possible has been made of the (inter)national standards and other homologation directives such as the KBOH/TNO homologation directive for wheelchairs.

The complete homologation directive as concerns the type test of the product group consists of eight chapters:

1. Introduction;
2. Administrative regulations;
3. The test: set up and administrative requirements;
4. Validity of type approval;
5. Measuring procedures;
6. Test requirements;
7. Overview of test requirements per KBOH cluster;
8. Literature.

2 Administrative regulations

2.1 General

The Administrative Regulations contain further descriptions of the test set up, further details will be added to the 'Agreement on quality research of technical aids for disabled persons', where applicable.

The requirements as to the administrative documentation to be submitted are also included in the Administrative Regulations.

Administrative requirements are necessary for a proper implementation for both the type test and the follow-up test. By carrying out follow-up tests it is continually examined whether the product still satisfies the requirements.

2.2 The agreement

General

In the 'Agreement on quality research of technical aids for disabled persons' (The Agreement) the conditions are laid down, among other things, under which the test is carried out.. Below you will find important items of the Agreement. They will be explained in separate chapters.

The test

Article 1.3:

"The Research shall comprise product tests and/or production method inspections as described in the Homologation Directive. The Principal undertakes to notify TNO, in the manner as described in the Homologation Directive, of the production method for the Product or of any changes in the production method for the Product and/or of any changes to the Product itself".

Article 1.4:

"The Principal undertakes to allow persons designated by TNO for this purpose at all times access to the premises of the Principal and its administrative records, in order to enable TNO to make itself acquainted with the production methods for the Product and the distribution thereof on the market".

Article 1.5:

"TNO may afford KBOH and/or persons acting by order of KBOH the opportunity to be present at the performance of measurements in the context of the Research, provided the Principal has given approval therefor in writing. In such case, TNO shall agree with KBOH and/or persons acting by order of KBOH that it/they shall be bound to secrecy as provided in article 3 of the Conditions".

Article 1.6:

"TNO shall carry out the Research within the term specified in the Homologation Directive".

The Follow-up test

Article 2.4:

“During the term of this Agreement, TNO shall have a right to repeat the Research, in whole or in part, by random testing. To this end, the Principal undertakes to continuously submit samples of the Product from the series production to TNO for inspection, and shall do so with a frequency as described in the Homologation Directive. In addition, TNO shall, as many and as often as TNO so deems desirable, obtain samples of the Product from sales outlets or other places to be selected under the sole responsibility of TNO. Only TNO shall be responsible for selecting samples without giving any guarantee as to the representativeness of such random sampling”.

Article 2.5:

“In performing the Research as provided in article 2.4, in such cases as specified in the Homologation Directive, TNO shall issue a follow-up test report to the Principal or do so, if it should turn out that any one or several of the samples of the Product and/or the production method no longer meet(s) the Requirements. In such case, TNO shall also notify KBOH that the Product no longer meets the Requirements”.

Article 2.6:

“The principal undertakes to keep such administrative records for the Research referred to in article 2.4 as will enable TNO to determine at all times the moment at which and the manner in which a sample of the Product was manufactured or assembled. In addition, the Principal shall maintain a quality control scheme such as to ensure that all specimens of the Product be manufactured in a uniform manner and in accordance with the Product as examined by TNO and the pertinent data simultaneously furnished to TNO”.

Use of the name KBOH or TNO

Article 3.2:

“If, after this Agreement has become operative, TNO finds that the Product meets the Requirements and consequently KBOH has included the Product on the GQ- List, and as long and to the extent TNO during the term of the Agreement has not determined that the Product does not or meet (no longer meets) the Requirements, the Principal shall be permitted for the sale of the Product to use in advertisements, in leaflets, on packaging materials or on labelling, the following text:

This product of the make: (as described under the acceptance number in the
type: approval report)

has been approved by TNO in accordance with the Requirements of
KBOH

The Principal undertakes to supply TNO with proofs of any proposed advertisements, leaflets, packaging materials or labelling containing this text. TNO reserves the right to forbid such publication if in TNO's judgement it could give rise to misleading product information”.

Applying the approval mark

Article 3.3:

“In addition, the Principal undertakes to provide all specimens of the Product meeting the Requirements and intended for the Dutch market with approval label to be supplied by TNO and to be affixed thereon in the manner as prescribed by the Homologation Directive. In case TNO should find that the Product no longer meets the Requirements, TNO shall have a right to forbid the Principal, with immediate effect, the use of the approval label on the specimens of the Product still in stock at the Principal”.

Non-compliance of the production

Article 3.4:

“In the event TNO determines that the Product no longer meets the Requirements, TNO shall have the right to forbid the Principal, with immediate effect, the use of the text provided in article 3.2 as well as any other use of the name of TNO and/or KBOH or after consulting KBOH to require that the Principal take any other measures, without prejudice to the provisions of article 2.5. The Principle shall be under obligation to cease the use of the name of TNO and/or KBOH forthwith, at first notice to this effect, or to take immediately such measures as are required by TNO and/or KBOH”.

3 The examination: set up and administrative requirements

3.1 Introduction

The examination consists of a Type approval and Follow-up test. In the latter a distinction is made in a product follow-up test and production control.

Any modifications to the product should be reported as outlined in the Administrative Regulations. This also applies to changes in the production process of the principal. Assembly of the Product by the importer is also considered as a production process.

3.2 Type approval

The type approval is carried out to determine whether the examined product meets the Requirements with regard to the specific type.

Application for a Type test

The application for a test advice shall be made with the KBOH:

Bureau Keuringen KBOH
P.O.Box 2072
3440 DB Woerden

Telephone: + 31 (0)348-436711
Telefaxnumber: + 31 (0)348-433257

The application as well as the technical and commercial documentation will be considered strictly confidential at the KBOH office and treated as such.

The order for the Type test is made to TNO by the manufacturer/importer or his authorised representative, by submitting the order form together with the test advice issued by the KBOH and by signing the Agreement. Standard order forms are sent by TNO upon request.

For shower aids TNO has appointed the Institute for Road Transport. The address is as follows:

TNO Road Vehicles Research Institute
Homologation Department
Schoemakerstraat 97 P.O. Box 60333
2628 VK Delft 2600 AE Delft

Phone: + 31 (0)15-2696385
Fax : + 31 (0)15-2620015

Samples to be submitted

For the approval test to be carried out one complete product shall be submitted, if applicable, plus an accessory to be indicated by TNO, as far as these have to be included in the test advice. The manufacturer shall see to it that the product is representative for the serial production.

Upon presentation the product should:

- be ready for use and compiled as indicated by TNO on the basis of the Test advice;
- be provided with a trade mark and type indication;
- bear an identification mark.

Specifically to fixedly positioned shower aids the following applies:

- fixing devices for fixing to the wall or floor.

Administrative documentation to be submitted

Together with the order form, the test advice issued by the KBOH and the signed Agreement, the following documents are to be handed in duplicate:

for all product groups:

- the list of details belonging to the order form, duly completed by the principal ordering the type approval;
- technical and commercial documentation concerning the product including the standard range of options;
- manual in Dutch at least including the following items:
 - . name and address of the manufacturer and/or importer;
 - . explanation of the application possibilities of the shower aid;
 - . explanation of the operational adjustments;
 - . explanation and location of operation devices;
 - . explanation of symbols, if applicable;
 - . maintenance instructions;
 - . cleaning, adjustment and lubrication instructions;
 - . the user manual should be written in clearly understandable Dutch;
 - . an assembly drawing with a complete parts list;
 - . detailed drawings of essential matters.

Drawings must be dated and provided with the manufacturer's name. Each drawing must include a name and drawing number/unique component number. The format should be A4 or A3 folded to A4.

Execution of Type approval

The test shall be performed in conformity with the procedure outlined in Chapter 5, Measuring procedure, using the test advice issued by KBOH stating the cluster for which the product has been designed and what homologation directive applies.

After completion of the measurements, successful finalisation of the test and drawing up the test report, the Principal shall be notified that the product can be obtained.

However, if the product fails the test, it will stay at TNO as long as the definitive approval has not been given or as long as the Principal has not withdrawn the test application.

Exceptions to this rule may be granted in consultation with TNO.

Reporting test results (test report)

The results of the type approval are recorded in a written report. This report includes at least the following items:

- a description of the product based on information supplied by the principal
- results of the measurements (measuring values)
- a ruling whether the Requirements are satisfied
- what models of the approved product also meet the Requirements (which are also admitted together with the approved type)
- in case of a deviation from the measuring method:
the nature and reason of the deviation
- photograph(s) of the product
- additional remarks and observations, e.g. in relation to safety aspects.

The report is sent in duplicate to the principal and, if the Requirements are met, to KBOH, Bureau Keuringen for entering on the list of approved products, the GQ-list.

3.3 Follow-up test

During the follow-up test it will be examined whether the product still meets the requirements and/or the product corresponds with the sample submitted for the Type approval.

In the Agreement it is not specified whether the follow-up test will be performed on the basis of periodical Product follow-up tests and/or periodical Production controls.

In the present situation many manufacturing companies are in the process of developing a verifiable system of quality care. At the moment it cannot be reasonably expected that all requirements in this respect will be satisfied. For this reason the companies may decide to opt for either a periodical Product follow-up test or a periodical Production control. Please note that a Product follow-up test covers every type of product placed on the GQ-list, whereas Production control relates to the location where the manufacturing/assembly of parts and/or end product takes place.

Especially when a principal wishes to have several Product follow-up tests and approved, it is recommendable to replace separate Product follow-up tests by a combined Production control.

The manufacturer should indicate the way in which the follow-up test is to be carried out:

- periodical Product follow-up test
- periodical Production control
- periodical sending of acknowledged production evaluation reports

Article 3.3. of the General Conditions TNO applies to documentation marked by the principal as 'Confidential' or 'Secret' and this documentation shall be treated as such.

The principal is under obligation to provide insight into the way in which the product is manufactured. This particularly concerns the materials used, the applied electronic components and the connecting techniques.

3.3.1 Product follow-up test

Start of Product follow-up test

In case the follow-up test consists of a periodical Product follow-up test, representative samples are examined at random of every type of product appearing on the GQ-list.

Periodical Product follow-up test:

For this purpose TNO requests the principal to supply samples of the product to be tested:

For shower aids the frequency is:

- 1 per 500 produced/delivered products with a minimum of 1 per year and a maximum of 4 per year.

The costs involved in this periodical Product follow-up test will be charged to the Principal.

***N.B. As regards shower aids please note that the Production control and Quality system certification are with reservation for the time being.**

The selection of the samples to be examined can be presented to the Principal by TNO, or after presentation by TNO left to the Principal who will guarantee the representativity of the sample.

Random Product follow-up test:

In addition to the above periodical Product follow-up test, TNO may at any time, whether requested by others or upon its own initiative, obtain samples of the product from sales outlets or other locations to be selected by TNO (see: Agreement, article 2.4).

Implementation of the Product follow-up test

This test consists of a full or partial performance of the measuring procedures outlined in Chapter 3.3.1 with the use of the test advice issued at the time by KBOH.

After the measurements have been taken, the Test has been successfully completed and the report has been finalised, the Principal will be notified that the product can be collected.

However, if the product fails the test it will stay at TNO as long as the definite approval has not been obtained or as long as the principal has not withdrawn his test application.

Reporting test results (Product follow-up test report)

The way in which the results of a Product follow-up test are reported depends on the findings.

No deviations

If it is not established during a Product follow-up test that:

1. the product deviates from the set Requirements, or
 2. the product design is adjusted without notification, or
 3. the production process has been adjusted without notification,
- the findings will be presented to the principal by means of a test report.

Deviations

If it is established during a Product follow-up test that:

1. the product deviates from the set Requirements, or
 2. the product design is adjusted without notification, or
 3. the production process has been adjusted without notification,
- the principal will be informed of this and may be temporarily denied the right (blocking) to use the name of TNO and/or KBOH. The principal must also stop applying the approval marks.

In case of a reported deviation the Principal should look into the cause of the deviation as established by TNO (e.g. in the production or used materials); his findings are to be reported to TNO in writing.

- A. If unintended deviations are observed in comparison with the initially tested (approved) type, the Principal has to restore the deviation concerned and its cause.

If these steps and the reported results are satisfactory in the opinion of TNO, the Principal may resume using the name TNO and/or KBOH and the application of the approval marks (unblocking).

- B. If in the opinion of TNO insufficient steps have been taken to improve the situation, the measurement concerned (or measurements) will be repeated for account of the principal with the use of three other samples (or components of these samples) from the same production series.

If these measurements have a positive result, the principal may resume using the name TNO and/or KBOH and the application of the approval marks is to be resumed.

If the above actions do not have a positive result within one month, TNO has the right to disallow the principal to use the name TNO and/or KBOH any further as well as the application of the approval marks.

The report about this will be presented to KBOH stating that the product type no longer meets the Requirements and is no longer eligible for entry on the GQ-list.

3.3.2 Production control

Start of the Production control

If the follow-up test is carried out by means of Production control, it is established whether the production process of the products entered on the GQ-list, complies with the NEN-ISO 9000 series (or EN-29000 series). It is checked if the quality system warrants that the supplied products satisfy the Requirements. This check takes place at the beginning of the period in which the approval mark is applied by the Principal and is repeated annually. In general, an initial production control will take more time than subsequent annual checks.

If it can be determined from the submitted evaluation report that the quality system of the products entered on the list matches the NEN-ISO 9000 series, it will be decided on this basis that the quality of the delivered products is sufficiently guaranteed. If the result of a production control is negative, a product follow-up test may still be performed.

The production control may be carried out in two ways:

- A. a visit to the company of one or several days:
TNO informs the principal when the assessment will be made.
Prior to the company visit the following documentation is to be sent to TNO (if available):
- quality handbook
 - organisation schedule
 - schedule: manufacturing process
 - company layout
 - recent annual report
- B. evaluation of a report including findings of a company assessment from an independent and certified institution dated less than one year ago: TNO shall request the Principal to send an assessment report.

Implementation of Product control

The implementation of the Test will be carried out on the basis of the documentation made available.

If a company visit is included in the production control, the different parts of the applicable standard will be discussed with a number of company officials and the realisation and compliance will be checked at random. A check is also made of the administrative records from which it can be assessed when and how a product is manufactured.

Reporting results (Production control report)

The way in which the results of a Production control are reported depends on the findings.

No deviations

If it is not established during a Production control that:

1. the product deviates from the set Requirements, or
 2. the product design is adjusted without notification, or
 3. the production process has been adjusted without notification,
- the findings will be presented to the principal by means of a test report.

Deviations

If it is established during a Production control that:

1. the product deviates from the set Requirements, or
 2. the product design is adjusted without notification, or
 3. the production process has been adjusted without notification,
- the principal will be informed of this and may be temporarily denied the right (blocking) to use the name of TNO and/or KBOH. The principal must also stop applying the approval marks.

In case of a reported deviation the Principal should look into the cause of the deviation as established by TNO (e.g. in the production or used materials); his findings are to be reported to TNO in writing.

- A. If unintended deviations are observed in comparison with the initially tested (approved) type, the Principal has to restore the deviation concerned and its cause.
If these steps and the reported results are satisfactory in the opinion of TNO, the Principal may resume using the name TNO and /or KBOH and the application of the approval marks.
- B. If in the opinion of TNO insufficient steps have been taken to improve the situation, the Production control may be replaced by a Product follow-up test as outlined at 3.3.1., for which this test will be carried out on three products after which, dependent on the findings, the normal frequency of Product follow-up tests will be taken into account again.
If these measurements have a positive result, the principal may resume using the name TNO and/or KBOH and the application of the approval marks is to be resumed.

If the above actions do not produce a positive result within one month, TNO has the right to disallow the Principal using the name TNO and/or KBOH any further as well as applying the approval marks.
The report concerned will be presented to KBOH stating that the Product no longer meets the Requirements and is therefore not eligible for entry on the GQ-list.

3.4 Adjustments

Reporting adjustments

Every adjustment to the product or substantial change in the production method or used materials must be reported by the Principal to TNO before the adjustment involved takes effect.

A change is reported by sending:

1. Drawings of the modification clearly stating the nature.
2. Short explanation of the adjustment.

It should also be stated if the original model will be cancelled or continues to exist alongside the reported adjustment. This should also be clear from the identification mark.

Additional Test

Having evaluated the adjustment on the basis of the supplied information, TNO shall inform the Principal whether the intended modification can be introduced without a further Test being performed or whether this Test is deemed necessary.

An additional Test will be performed for account of the Principal of which he will be informed accordingly by TNO.

Dependent in the nature of the modification, an additional Test may comprise a full or partial Type approval or Production control (as outlined in item 3.2 or 3.3.2).

Reporting results (Extension report)

If an additional Test is performed the results of this test will be recorded in a written report in accordance with item 3.4 (extension report).

On the basis of the information supplied by the Principal and the findings of TNO, the Principal will be notified about the nature of the modification:

- a. fitting within an approved product type (with the same admission number)
- b. another product type, substantially deviating from an approved product type (with a different admission number).

Furthermore, the results of an additional Test will be recorded in a written report including the conclusion whether the Requirements are satisfied. The report will be sent in duplicate to the Principal, and, if the Requirements are met, to KBOH, Bureau Keuringen, for the purpose of entering the Product on the GQ-list.

If the Principal does not arrange for an additional Test, although TNO seems this necessary, the Approval is cancelled and reported to KBOH. The Product will no longer qualify for entry on the GQ-list. The application of approval marks will be stopped.

3.5 Extension of the validity of the approval mark

If the validity of the approval mark expires at the end of the year, an additional test is required. If so, the product is to be evaluated on the basis of the homologation directive applicable to that year. The procedure to be followed is the same as the procedure involved in adjustments (item 3.4), for which a new test is also to be applied for. At the moment a Principal reports a product to TNO for extension of the approval mark, TNO shall notify KBOH that a new test advice is to be issued.

3.6 Approval marks

General

When the Agreement is signed and the full type test has been successfully completed, the Principal having ordered the type test is under obligation to apply the approval marks to all products, to be put on the Dutch market, that fall under the approved type. It is obviously also permitted to apply the approval mark to approved products meant for markets abroad.

The approval mark is a self-adhesive light-grey sticker with black imprint that can be adhered to a rigid surface.

On the approval mark the following details are printed:

- Approved
- KBOH-TNO
- Homologation directive
- Admission number
- Make/manufacture
- Type indication
- rising serial number



Issue of approval marks

The first series of approval marks can be issued by TNO when the product has passed the type test and the Agreement has been signed. It will usually consist of 50 copies or a multiple up to a maximum of 500 copies. For different numbers a special arrangement can be made between TNO and the Principal.

Ordering approval marks

Approval marks can be ordered by means of a written order sent to TNO (see enclosed form). Delivery will take 3 to 4 weeks.

To avoid stagnation of production/sales due to lack of approval marks, orders should be made in timely fashion.

Cost of approval marks

The price of the approval mark is NLG 2.-- a piece, with a minimum of 100. When ordering 50 pieces the price is NLG 4.-- each and in case of orders of less than 50 the price is NLG 6.-- each with a minimum of 10 pieces.

Application of approval marks

The approval mark should be applied to the frame of the shower aid on a non-detachable part.

3.7 Price and payment

The price of the Type approval is subject to the cluster of the shower aid, particularly the distinction moveable/non-moveable, design sitting support and way of propulsion.

Costs per Type test: (at the start)

| | |
|---|-------------|
| Non-moveable standing/simple sitting support (cluster 1, 2, 3 and 4) | NLG 1.875,- |
| Non-moveable sitting/total/care support (cluster 5, 6, 10 and 13) | NLG 2.400,- |
| Moveable sitting/total/care support (cluster 7, 8, 9, 10, 11 and 14) | NLG 5.885,- |

Costs per Product follow-up test: (annually)

| | |
|---|------------------|
| Non-moveable standing/simple sitting support (cluster 1, 2, 3 and 4) | MAX. NLG 990,- |
| Non-moveable sitting/total/care support (cluster 5, 6, 10 and 13) | MAX. NLG 1.210,- |
| Moveable sitting/total/care support (cluster 7, 8, 9, 10, 11 and 14) | NLG 2.400,- |

Costs per Production control

| | |
|-------------------------------------|--------------------|
| Inspection of quality system | according to offer |
| Review of report mad by third party | according to offer |
| Quality system control | according to offer |

The above prices exclude VAT (Value Added Tax)

Terms of payment are as follows:

Type test:

- After sending the test report a separate invoice is sent stating the costs of the Type test as charged.
- Prior to the Type test an offer can be requested if a total Type test for a Product is not intended. For example, in case of extension or when a coherent group is submitted (family).

Product follow-up test:

- After sending the test report a separate invoice is sent stating the costs of the Follow-up test as offered.

Production control:

- After sending the test report a separate invoice is sent stating the costs of the Product control test as offered.

3.8 Term

Type approval:

The type approval will be completed by means of a report not later than 3 months after the application has been made.

If it is observed during the test that the requirements are not met, so that no approval can be given at the end of the type approval, the principal shall immediately be notified accordingly.

This may imply an extension of the set term.

Follow-up test:

In case of a production control TNO, after consultation with the Principal, shall issue a delivery date for the report.

4 Validity of type approval

The issued type approval is valid for a maximum period of three years following the cancellation of these test requirements. During these three years the follow-up tests will be performed on the basis of the test requirements according to which the type approvals have been awarded.

If the manufacturer/importer does not comply with the regulations of the Agreement or the administrative obligation included in this homologation directive, the approval will be cancelled with immediate effect.

To prevent a Product being removed from the List an extension is required of the validity of the approval (see item 3.2).

5 Measuring procedures

See:

KBOH-TNO Homologation Directive D 01

Definitions and measuring procedures

Aids for showering, showering in a sitting position

KBOH, November 1997

6 Test requirements

6.1 Introduction test requirements

This chapter of the homologation directive describes the test requirements.

These are classified into the following main features:

- 6.2 General
- 6.3 Sitting and performing activities
- 6.4 Making transfers
- 6.5 Moving
- 6.6 Area of application
- 6.7 Strength and durability
- 6.8 Safety and maintenance

As regards these test requirements, the required values are the extreme limits including measuring tolerances.

6.2 General

Property 0.1 Total shower aid

Test requirement: No evidently poor usefulness of the shower aid (see annex 1 for examples).

Property 0.2 Product information

Test requirement: Each shower aid has to be provided with the necessary information for safe use, taking into account the knowledge and educational level of the user, that should include the manufacturer's identification. This information consists of indications on the labels and in the manual.

The information for the safe use of the aid should to the extent to which this is possible and useful, be present on the aid itself and/or the unit packaging, or, if applicable, on the stock packaging. If labelling per unit is not possible the information should occur on a manual provided by one or more aids. All shower aids should have a manual enclosed in the packaging.

6.3 Sitting and performing activities

Property: 1.1.01.01.01 Wedge angle ϕ

Test requirement $-4^\circ \leq \phi \leq 4^\circ$.

Property: 1.1.01.01.02 Wedge angle ϕ

Test requirement: $0^\circ \leq \phi \leq 10^\circ$.

Property: 1.1.01.01.03 Wedge angle ϕ

Test requirement: $4^\circ \leq \phi \leq 14^\circ$.

Property: 1.1.01.01.04 Wedge angle ϕ

Test requirement: ϕ EI, PVT of PVG,
at least 60% or the area $4^\circ \leq \phi \leq 14^\circ$.

Property: 1.1.01.01.05 Transfer angle ϕ

Test requirement: $\phi \leq 4^\circ$.

Property: 1.1.01.02.01 Angle α

Test requirement $90^\circ \leq \alpha \leq 100^\circ$.

Property: 1.1.01.02.02 Angle α

Test requirement: α at least EI,
 α at least adjustable over 60% of the area
 $90^\circ \leq \alpha \leq 110^\circ$.

Property: 1.1.02.02.01 Adjustment of angle ϕ (transfer angle) user

Test requirement: Adjustable by user possible, i.e.:

- no more than thorax free from back rest;
- handle: operating force ≤ 60 N;
- turning knob: $40 \text{ mm} \leq \text{diameter} \leq 100 \text{ mm}$
acceptable moment (Nm):
 $\leq 0,05 * \text{radius knob (mm)}$ in case of transmission
by friction;
 $\leq 0,1 * \text{radius knob (mm)}$ in case of positive-fit
knob.

Property: 1.1.02.02.02 Adjustment of angle ϕ (transfer angle) attendant

Test requirement: Adjustment by attendant possible, i.e.:

- handle: operating force ≤ 60 N;
- turning knob: $40 \text{ mm} \leq \text{diameter} \leq 100 \text{ mm}$
acceptable moment (Nm):
 $\leq 0,05 * \text{radius knob (mm)}$ in case of transmission by friction;
 $\leq 0,1 * \text{radius knob (mm)}$ in case of positive-fit knob.

Property: 1.1.03.01.01 Seat depth

Test requirement: Seat depth ≥ 200 mm.

Property: 1.1.03.01.02 Seat depth

Test requirement: $260 \text{ mm} \leq \text{seat depth} \leq 550 \text{ mm}$.

Property: 1.1.03.02.01 Seat width

Test requirement: $290 \text{ mm} \leq \text{seat width} \leq 540 \text{ mm}$.

Property: 1.1.03.02.02 Seat width

Test requirement: Seat width ≥ 370 mm.

Property: 1.1.03.03.01 Backrest height

Test requirement: $350 \text{ mm} \leq \text{backrest height} \leq 550 \text{ mm}$.

Property: 1.1.03.03.02 Backrest height

Test requirement: $450 \text{ mm} \leq \text{backrest height} \leq 630 \text{ mm}$.

Property: 1.1.03.03.03 Backrest height

Test requirement: $460 \text{ mm} \leq \text{backrest height} \leq 730 \text{ mm}$.

Property: 1.1.03.06.02 Seat height

Test requirement: Seat height at least EI
 $330 \text{ mm} \leq \text{seat height} \leq 540 \text{ mm}$.

Property: 1.1.03.07 Lower leg support

Test requirement: Heel or calf support present.

Property: 1.1.03.08 Foot support design

Test requirement: Opening between footplates ≤ 50 mm.

Property: 1.1.05.02 Care height

Test requirement: $680 \text{ mm} \leq \text{care height} \leq 840 \text{ mm}$.

Property: 1.1.05.06 Removing/placing bed-pan

Test requirement: If bed-pan is present, overlap with toilet opening at least 250 mm, measured from the back of the toilet opening. Largest width at least 120 mm.

6.4 Making transfer

Property: 1.2.01.01 Get up space

Test requirement: Get up width per leg ≥ 150 mm
depth compared to seat on floor ≥ 0 mm.

Property: 1.2.01.03 Shift over distance

Test requirement: Shift over distance ≤ 100 mm.

Property: 1.2.01.04 Shift over height

Test requirement: Shift over distance in case of loaded seat ≤ 50 mm.

Property: 1.2.01.05 Shift over depth

Test requirement: Shift over depth ≥ 200 mm.

Property: 1.2.02.01 Removing of armrest, user

Test requirement: Removing or replacing by user possible, i.e.:

- locking or unlocking knobs should be accessible for locking and unlocking;
- no complex body movements and/or operations for removing or replacing;
- no evidently bad functioning with regard to removing or replacing;
- no difficult and/or very precise positioning with regard to components to be replaced;
- no more than lumbar free from back rest;
- after removing armrests should remain attached to shower aid.

Property: 1.2.02.02 Removing of armrest, attendant

- Test requirement
- Removing or replacing by attendant possible, i.e.:
- locking or unlocking knobs should be accessible for locking or unlocking;
 - no complex body movements and/or operations for removing or replacing;
 - no evidently bad functioning with regard to removing or replacing;
 - no difficult and/or very precise positioning with regard to components to be replaced;
 - after removing, armrests should remain attached to shower aid.

Property: 1.2.02.03 Removing of footrest/legrest, user

- Test requirement:
- Removing or replacing by user possible, i.e.:
- locking or unlocking knobs should be accessible for locking or unlocking;
 - no complex body movements and/or operations for removing or replacing;
 - no evidently bad functioning with regard to removing or replacing;
 - no difficult and/or very precise positioning with regard to components to be replaced;
 - no more than lumbar free from back rest;
 - after removing foot/legrests should remain attached to shower aid.

Property: 1.2.02.04 Removing foot/legrest attendant

- Test requirement:
- Removing or replacing by attendant possible, i.e.:
- locking or unlocking knobs should be accessible for locking or unlocking;
 - no complex body movements and/or operations for removing or replacing;
 - no evidently bad functioning with regard to removing or replacing;
 - no difficult and/or very precise positioning with regard to components to be replaced;
 - after removing foot/legrests should remain attached to shower aid.

Property: 1.2.03.01.01 Get up height

Test requirement: $680 \text{ mm} \leq \text{get up height} \leq 840 \text{ mm}$.

Property: 1.2.03.01.02 Get up height

Test requirement: Get up height $< 680 \text{ mm}$.

Property: 1.2.03.01.03 Transfer height

Test requirement: $450 \text{ mm} \leq \text{transfer height} \leq 600 \text{ mm}$.

6.5 Moving

Property: 1.3.01.03 Manoeuvring force

Test requirement: Pushing force start/continuous $\leq 45 \text{ N}$
Pushing force turning rolling direction $\leq 175 \text{ N}$.

Property: 1.3.02.03.01 Self-propelling force (hand)

Test requirement: Force $\leq 45 \text{ N}$.

Property: 1.3.02.03.02 Self-propelling force (leg)

Test requirement: Force $\leq 45 \text{ N}$.

Property: 1.3.02.04 Tripping space

Test requirement: Tripping width per leg $\geq 150 \text{ mm}$
Depth compared to seat on floor $\geq 0 \text{ mm}$.

Property:: 1.3.02.05 Tripping height

Test requirement: Tripping height at least EI
 $330 \text{ mm} \leq \text{tripping height} \leq 540 \text{ mm}$.

Property: 1.3.03.01 Ease of operation braking system, user

Test requirement: Operation unit accessible and operable by user:

- no more than thorax free from the backrest;
- no complex body movement;
- switching on/off operating force $\leq 60 \text{ N}$;
- no evidently bad functioning.

Property: 1.3.03.02 Ease of operation braking system attendant

Test requirement: Operation unit accessible and operable by attendant: manual operation:

- no complex body movement;
- switching on/off operating force ≤ 60 N;
- no evidently bad functioning foot operation;
- operating force ≤ 180 N.

6.6 Area of application

Property: 1.4.01.01 Surface

Test requirement: Width ≤ 650 mm.

Property: 1.4.01.01 Surface

Test requirement: Width ≤ 700 mm.

Property: 1.4.02.01 Ease of operation reducing size/disassembly

Test requirement: Ease of operation not evidently bad:

- reducing must be possible without the risk of getting injured;
- no complex operation activities;
- without use of body weight;
- operable by one person.

Property: 1.4.02.02 Ease of moving

Test requirement: Weight of shower aid ≤ 10 kg.

Property: 1.4.03.02 Turning radius/diagonal

Test requirement: Turning radius ≤ 850 mm and diagonal ≤ 1200 mm.

Property: 1.4.03.03 Turning radius/diagonal

Test requirement: Turning radius ≤ 900 mm and diagonal ≤ 1400 mm.

Property: 1.4.04.02 Overlap toilet opening

Test requirement: In case of fitting over toilet of 39 cm high (2 models) with seat down the overlap of the toilet opening shower aid with toilet opening ≥ 250 mm measured from the back of the toilet opening.

6.7 Strength and durability

Property: 2.1.01.01 Static strength

Test requirement: Following the completion of the strength test the shower aid should function normally, i.e.:

- no break or crack formation should occur;
- no deformation should occur.

Property: 2.1.01.02 Impact resistance

Test requirement: Following the completion of the strength test the shower aid should function normally, i.e.:

- no break or crack should occur;
- no deformation should occur.

Property: 2.1.02.03 Fixing of laque

Test requirement: Fixing should be at least class 0 - 1.

Property: 2.1.02.04 Corrosion Sensitivity

Test requirement: After 96 hours maximum Re2 and maximum Ox3:

- parts accessible by user and/or attendant;
- surfaces of parts shifting against or over each other by an adjustment possibility (EI/PVT/PVG) and/or moving (folding, turning away).

Property: 2.1.03.01 Frame

Test requirement: No excessive clearance should occur, no crooked or inclined construction.

Property: 2.1.03.02 Wheels and wheel suspension

Test requirement: No wheels running out of true, no buckle, maintenance free bearings suitable for use in wet conditions.

Property: 2.1.03.03 Brakes

Test requirement: Proper fixing to frame.

Property: 2.1.03.04 Fixing of support elements

Test requirement: Proper fixing to frame.
If the position of the support elements are adjustable without unambiguous stop, the workable adjustments range should be indicated.

6.8 Safety and maintenance

Property: 2.2.01.01.01 Stability of tipping, loaded

Test requirement: Tipping angle in all directions $\geq 5^\circ$.

Property: 2.2.01.02 Displacement resistant

Test requirement: Displacement resistance ≥ 200 N.

Property: 2.2.01.03 Maximum unevenness

Test requirement: The shower aid should be able to compensate a difference in level of 3 mm.

Property: 2.2.01.06 Protection of moving parts

Test requirement: No risk of hands or fingers getting caught between moving parts.

Property: 2.2.01.07 Sharp parts

Test requirement: No sharp parts or burrs should be present on place accessible to the user and attendant.

Property: 2.2.02.02 Accessibility for cleaning purposes

Test requirement: Changes in shape or openings in the seat and backrest that get in contact with the user must be well accessible for cleaning purposes. The frame of the pan should also be easily accessible for cleaning.

7 Overview of test requirements per KBOH cluster

7.1 Introduction

This chapter of the homologation directive contains an overview indicating which test requirements (see chapter 6) are applicable to a specific cluster. By means of the tables it can be determined what test requirements a shower aid should meet to be approved for one or several clusters.

In the table you will find on the vertical axis the feature numbers and names for which test requirements have been formulated and on the horizontal axis the cluster numbers used by KBOH.

The crosses in the tables indicate which requirement stated on the horizontal axis the shower aid should meet to be qualified for the cluster stated on the vertical axis. A shower aid is eligible for classification and approval into a specific cluster if it complies with all requirements set to the cluster concerned.

In the table you will also find the letter 'm' instead of a cross. This test requirement only applies if the part concerned is provided with the shower aid. This concerns a possible additional accessory to the product described by KBOH within the cluster involved.

The next sessions include the tables for standing support/simple sitting support (§7.2), for the non-moveable sitting support, total support and care support (§ 7.3) and the moveable sitting support, total support and care support (§ 7.4).

x = applicable

0 = not applicable

m = possibly applicable, if present

7.2 Test requirements standing support/simple sitting support (non-moveable)

1

FUNCTIONAL

1.1

SITTING AND PERFORMING ACTIVITIES

| 1.1.01 | Sitting position | 1 | 2 | 3 | 4 |
|--------|---|---|---|---|---|
| | 1.1.01.01.01 wedge angle ϕ | x | x | x | x |
| | 1.1.01.01.02 wedge angle ϕ | 0 | 0 | 0 | 0 |
| | 1.1.01.01.03 wedge angle ϕ | 0 | 0 | 0 | 0 |
| | 1.1.01.01.04 wedge angle ϕ | 0 | 0 | 0 | 0 |
| | 1.1.01.01.05 transfer angle ϕ | 0 | 0 | 0 | 0 |
| | 1.1.01.02.01 angle α | 0 | 0 | m | m |
| | 1.1.01.02.02 angle α | 0 | 0 | 0 | 0 |
| 1.1.02 | Ease of operation angle adjustments | | | | |
| | 1.1.02.02.01 adjustment of angle ϕ (transfer angle) user | 0 | 0 | 0 | 0 |
| | 1.1.02.02.02 adjustment of angle ϕ (transfer angle) attendant | 0 | 0 | 0 | 0 |
| 1.1.03 | Dimensions support components | | | | |
| | 1.1.03.01.01 seat depth | x | x | 0 | 0 |
| | 1.1.03.01.02 seat depth | 0 | 0 | x | x |
| | 1.1.03.02.01 seat width | 0 | 0 | 0 | 0 |
| | 1.1.03.02.02 seat width | x | x | x | x |
| | 1.1.03.03.01 backrest height | 0 | 0 | m | m |
| | 1.1.03.03.02 backrest height | 0 | 0 | 0 | 0 |
| | 1.1.03.03.03 backrest height | 0 | 0 | 0 | 0 |
| | 1.1.03.06.02 seat height | 0 | 0 | 0 | 0 |
| | 1.1.03.07 lowerleg support | 0 | 0 | 0 | 0 |
| | 1.1.03.08 footrest design | 0 | 0 | x | x |
| 1.1.05 | Activity space | | | | |
| | 1.1.05.02 care height | 0 | 0 | 0 | 0 |
| | 1.1.05.06 removing/placing bed pan | 0 | 0 | 0 | 0 |

| | | | | | |
|---------------|---|----------|----------|----------|----------|
| 1.2 | <u>MAKING A TRANSFER</u> | | | | |
| 1.2.01 | Transfer space | 1 | 2 | 3 | 4 |
| | 1.2.01.01 get up space | 0 | 0 | x | x |
| | 1.2.01.03 shift over distance | 0 | 0 | 0 | 0 |
| | 1.2.01.04 shift over height | 0 | 0 | x | 0 |
| | 1.2.01.05 shift over depth | 0 | 0 | x | 0 |
| 1.2.02 | Ease of operation | | | | |
| | 1.2.02.01 removability armrest user | m | 0 | m | 0 |
| | 1.2.02.02 removability armrest attendant | 0 | 0 | 0 | 0 |
| | 1.2.02.03 removability footrest/legrest user | 0 | 0 | m | m |
| | 1.2.02.04 removability footrest/legrest attendant | 0 | 0 | 0 | 0 |
| 1.2.03 | Dimensions for transfer | | | | |
| | 1.2.03.01.01 get up height | x | x | 0 | 0 |
| | 1.2.03.01.02 get up height | 0 | 0 | x | x |
| | 1.2.03.01.03 transfer height | 0 | 0 | 0 | 0 |
| 1.3 | <u>MOVING</u> | | | | |
| 1.4 | <u>AREA OF APPLICATION</u> | | | | |
| 1.4.01 | Placing space | | | | |
| | 1.4.01.01 surface | 0 | 0 | 0 | 0 |
| | 1.4.01.03 surface | 0 | 0 | 0 | 0 |
| 1.4.02 | Moveability | | | | |
| | 1.4.02.01 ease of operation folding/disassembly | x | m | x | m |
| | 1.4.02.02 ease of moving | 0 | x | 0 | x |
| 1.4.03 | Manoeuvrability | | | | |
| | 1.4.03.02 turning circle/diagonal | 0 | 0 | 0 | 0 |
| | 1.4.03.03 turning circle/diagonal | 0 | 0 | 0 | 0 |
| 1.4.04 | Use on top of toilet | | | | |
| | 1.4.04.02 overlap toilet opening | 0 | 0 | 0 | 0 |

| | | | | | |
|---------------|---|----------|----------|----------|----------|
| 2 | TECHNICAL | | | | |
| 2.1 | <u>STRENGTH AND DURABILITY</u> | | | | |
| 2.1.01 | Strength | 1 | 2 | 3 | 4 |
| | 2.1.01.01 static strength | x | x | x | x |
| | 2.1.01.02 impact strength | x | x | x | x |
| 2.1.02 | Durability | | | | |
| | 2.1.02.03 fixing of paint/coating | x | x | x | x |
| | 2.1.02.04 corrosion resistance | x | x | x | x |
| 2.1.03 | Technical quality of construction | | | | |
| | 2.1.03.01 frame | x | x | x | x |
| | 2.1.03.02 wheels and wheel suspension | 0 | 0 | 0 | 0 |
| | 2.1.03.03 brakes | 0 | 0 | 0 | 0 |
| | 2.1.03.04 fixing of support element | x | x | x | x |
| 2.2 | <u>SAFETY AND MAINTENANCE</u> | | | | |
| 2.2.01 | Safety | | | | |
| | 2.2.01.01.01 stability tipping, loaded | 0 | x | 0 | x |
| | 2.2.01.02 shifting resistance | 0 | x | 0 | x |
| | 2.2.01.03 maximum unevenness | 0 | x | 0 | x |
| | 2.2.01.06 protection against moving parts | x | x | x | x |
| | 2.2.01.07 sharp parts | x | x | x | x |
| 2.2.02 | Maintenance | | | | |
| | 2.2.02.02 accessibility for cleaning purposes | x | x | x | x |

7.3 Test requirements sitting support/total support/care support (non-moveable)

1

FUNCTIONAL

1.1

SITTING AND PERFORMING ACTIVITIES

1.1.01

Sitting position

| | 5a | 5b | 6 | 10a | 10b | 13 |
|------------------------------------|----|----|---|-----|-----|----|
| 1.1.01.01.01 wedge angle ϕ | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.1.01.01.02 wedge angle ϕ | x | x | x | 0 | 0 | 0 |
| 1.1.01.01.03 wedge angle ϕ | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.1.01.01.04 wedge angle ϕ | 0 | 0 | 0 | x | x | x |
| 1.1.01.01.05 transfer angle ϕ | 0 | 0 | 0 | x | 0 | m |
| 1.1.01.02.01 angle α | x | x | x | x | x | 0 |
| 1.1.01.02.02 angle α | 0 | 0 | 0 | 0 | 0 | x |

1.1.02

Ease of operation angle adjustments

| | | | | | | |
|---|---|---|---|---|---|---|
| 1.1.02.02.01 adjustment of angle ϕ (transfer angle) user | 0 | 0 | 0 | x | 0 | 0 |
| 1.1.02.02.02 adjustment of angle ϕ (transfer angle) attendant | 0 | 0 | 0 | 0 | 0 | m |

1.1.03

Dimensions support components

| | | | | | | |
|-------------------------------|---|---|---|---|---|---|
| 1.1.03.01.01 seat depth | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.1.03.01.02 seat depth | x | x | x | x | x | x |
| 1.1.03.02.01 seat width | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.1.03.02.02 seat width | x | x | x | x | x | x |
| 1.1.03.03.01 back rest height | x | x | x | 0 | 0 | 0 |
| 1.1.03.03.02 back rest height | 0 | 0 | 0 | x | x | 0 |
| 1.1.03.03.03 back rest height | 0 | 0 | 0 | 0 | 0 | x |
| 1.1.03.06.02 seat height | 0 | 0 | 0 | x | x | x |
| 1.1.03.07 lower legsupport | 0 | 0 | 0 | x | x | x |
| 1.1.03.08 footrest design | x | x | x | x | x | x |

1.1.05

Activity space

| | | | | | | |
|--------------------------------|---|---|---|---|---|---|
| 1.1.05.02 care height | 0 | 0 | 0 | 0 | 0 | x |
| 1.1.05.06 removing/placing pan | 0 | 0 | 0 | m | m | m |

| | | | | | | | |
|---------------|---|-----------|-----------|----------|------------|------------|-----------|
| 1.2 | <u>MAKING A TRANSFER</u> | | | | | | |
| 1.2.01 | Transfer space | 5a | 5b | 6 | 10a | 10b | 13 |
| | 1.2.01.01 get up space | x | 0 | x | x | 0 | 0 |
| | 1.2.01.03 shift over distance | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.2.01.04 shift over height | 0 | x | 0 | x | 0 | 0 |
| | 1.2.01.05 shift over depth | 0 | x | 0 | x | 0 | 0 |
| 1.2.02 | Ease of operation | | | | | | |
| | 1.2.02.01 removability armrest user | m | x | m | x | x | 0 |
| | 1.2.02.02 removability armrest attendant | 0 | 0 | 0 | 0 | 0 | x |
| | 1.2.02.03 removability footrest/legrest user | m | m | m | x | 0 | 0 |
| | 1.2.02.04 removability footrest/legrest attendant | 0 | 0 | 0 | 0 | m | x |
| 1.2.03 | Dimensions for transfer | | | | | | |
| | 1.2.03.01.01 get up height | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.2.03.01.02 get up height | x | 0 | x | x | 0 | 0 |
| | 1.2.03.01.03 transfer height | 0 | x | 0 | 0 | 0 | 0 |
| 1.3 | <u>MOVING</u> | | | | | | |
| 1.4 | <u>AREA OF APPLICATION</u> | | | | | | |
| 1.4.01 | Placing space | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.4.01.01 surface | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.4.01.03 surface | | | | | | |
| 1.4.02 | Moveability | | | | | | |
| | 1.4.02.01 ease of operation folding/disassembly | x | x | m | x | x | x |
| | 1.4.02.02 ease of moving | 0 | 0 | x | 0 | 0 | 0 |
| 1.4.03 | Manoeuvrability | | | | | | |
| | 1.4.03.02 turning radius/diagonal | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.4.03.03 turning radius/diagonal | 0 | 0 | 0 | 0 | 0 | 0 |

| 1.4.04 | Use on top of toilet | 5a | 5b | 6 | 10a | 10b | 13 |
|---------------|---|----|----|---|-----|-----|----|
| | 1.4.04.02 overlap toilet opening | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | TECHNICAL | | | | | | |
| 2.1 | <u>STRENGTH AND DURABILITY</u> | | | | | | |
| 2.1.01 | Strength | | | | | | |
| | 2.1.01.01 static strength | x | x | x | x | x | x |
| | 2.1.01.02 impact strength | x | x | x | x | x | x |
| 2.1.02 | Durability | | | | | | |
| | 2.1.02.03 fixing of paint/coating | x | x | x | x | x | x |
| | 2.1.02.04 corrosion resistance | x | x | x | x | x | x |
| 2.1.03 | Technical quality of construction | | | | | | |
| | 2.1.03.01 frame | x | x | x | x | x | x |
| | 2.1.03.02 wheels and wheel suspension | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2.1.03.03 brakes | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2.1.03.04 fixing of support elements | x | x | x | x | x | x |
| 2.2 | <u>SAFETY AND MAINTENANCE</u> | | | | | | |
| 2.2.01 | Safety | | | | | | |
| | 2.2.01.01.01 stability tipping, loaded | 0 | 0 | x | x | x | x |
| | 2.2.01.02 shifting resistance | 0 | 0 | x | x | x | x |
| | 2.2.01.03 maximum unevenness | 0 | 0 | x | x | x | x |
| | 2.2.01.06 protection against moving parts | x | x | x | x | x | x |
| | 2.2.01.07 sharp parts | x | x | x | x | x | x |
| 2.2.02 | Maintenance | | | | | | |
| | 2.2.02.02 accessibility for cleaning purposes | x | x | x | x | x | x |

7.4 Test requirements sitting support/total support/care support (moveable)

1 FUNCTIONAL

1.1 SITTING AND PERFORMING ACTIVITIES

| 1.1.01 | Sitting position | 7 | 8a | 8b | 9 | 11a | 11b | 12 | 14 |
|--------|--|---|----|----|---|-----|-----|----|----|
| | 1.1.01.01.01 wedge angle ϕ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.1.01.01.02 wedge angle ϕ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.1.01.01.03 wedge angle ϕ | x | x | x | x | 0 | 0 | 0 | 0 |
| | 1.1.01.01.04 wedge angle ϕ | 0 | 0 | 0 | 0 | x | x | x | x |
| | 1.1.01.01.05 transfer angle ϕ | 0 | 0 | 0 | 0 | x | 0 | x | m |
| | 1.1.01.02.01 angle α | x | x | x | x | x | x | x | 0 |
| | 1.1.01.02.02 angle α | 0 | 0 | 0 | 0 | 0 | 0 | 0 | x |
| 1.1.02 | Ease of operation angle adjustments | | | | | | | | |
| | 1.1.02.02.01 adjustment of angle ϕ (transfer angle) user | 0 | 0 | 0 | 0 | x | 0 | 0 | 0 |
| | 1.1.02.02.02 adjustment of angle ϕ (transfer angle) attendant | 0 | 0 | 0 | 0 | 0 | 0 | x | m |
| 1.1.03 | Dimensions support components | | | | | | | | |
| | 1.1.03.01.01 seat depth | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.1.03.01.02 seat depth | x | x | x | x | x | x | x | x |
| | 1.1.03.02.01 seat width | 0 | x | x | 0 | x | x | 0 | 0 |
| | 1.1.03.02.02 seat width | x | 0 | 0 | x | 0 | 0 | x | x |
| | 1.1.03.03.01 back rest height | x | x | x | x | 0 | 0 | 0 | 0 |
| | 1.1.03.03.02 back rest height | 0 | 0 | 0 | 0 | x | x | x | 0 |
| | 1.1.03.03.03 back rest height | 0 | 0 | 0 | 0 | 0 | 0 | 0 | x |
| | 1.1.03.06.02 seat height | m | x | x | x | x | x | x | x |
| | 1.1.03.07 lower legrest | 0 | 0 | 0 | 0 | x | x | x | x |
| | 1.1.03.08 footrest design | 0 | x | x | x | x | x | x | x |
| 1.1.05 | Activity space | | | | | | | | |
| | 1.1.05.02 care height | 0 | 0 | 0 | 0 | 0 | 0 | 0 | x |
| | 1.1.05.06 removing/placing pan | 0 | m | m | m | m | m | m | m |

| 1.2 | | <u>MAKING A TRANSFER</u> | | | | | | | |
|---------------|---|---------------------------------|-----------|-----------|----------|------------|------------|-----------|-----------|
| 1.2.01 | Transfer space | 7 | 8a | 8b | 9 | 11a | 11b | 12 | 14 |
| | 1.2.01.01 get up space | x | x | 0 | x | x | 0 | x | 0 |
| | 1.2.01.03 shift over distance | 0 | 0 | x | 0 | x | 0 | 0 | 0 |
| | 1.2.01.04 shift over height | 0 | 0 | x | 0 | x | 0 | 0 | 0 |
| | 1.2.01.05 shift over depth | 0 | 0 | x | 0 | x | 0 | 0 | 0 |
| 1.2.02 | Ease of operation | | | | | | | | |
| | 1.2.02.01 removability armrest user | m | x | x | 0 | x | x | 0 | 0 |
| | 1.2.02.02 removability armrest attendant | 0 | 0 | 0 | x | 0 | 0 | x | x |
| | 1.2.02.03 removability footrest/legrest user | m | x | 0 | 0 | x | 0 | 0 | 0 |
| | 1.2.02.04 removability footrest/legrest attendant | 0 | 0 | 0 | x | 0 | m | x | m |
| 1.2.03 | Dimensions for transfer | | | | | | | | |
| | 1.2.03.01.01 get up height | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.2.03.01.02 get up height | 0 | x | 0 | x | x | 0 | x | 0 |
| | 1.2.03.01.03 transfer height | 0 | 0 | x | 0 | 0 | 0 | 0 | 0 |
| 1.3 | <u>MOVING</u> | | | | | | | | |
| 1.3.01 | Push facility | | | | | | | | |
| | 1.3.01.03 manoeuvring force | x | x | x | x | x | x | x | x |
| 1.3.02 | Independent propulsion | | | | | | | | |
| | 1.3.02.03.01 force self-propulsion (hand) | m | x | x | 0 | x | x | 0 | m |
| | 1.3.02.03.02 force self-propulsion (leg) | x | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.3.02.04 tripple space | x | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1.3.02.05 tripple height | x | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

| | | 7 | 8a | 8b | 9 | 11a | 11b | 12 | 14 |
|---------------|---|---|----|----|---|-----|-----|----|----|
| 1.3.03 | Ease of operation braking system | | | | | | | | |
| | 1.3.03.01 ease of operation user | x | x | x | 0 | x | x | 0 | 0 |
| | 1.3.03.02 ease of operation attendant | x | x | x | x | x | x | x | x |
| 1.4 | <u>AREA OF APPLICATION</u> | | | | | | | | |
| 1.4.01 | Placing space | | | | | | | | |
| | 1.4.01.01 surface | x | 0 | 0 | x | 0 | 0 | x | x |
| | 1.4.01.03 surface | m | x | x | 0 | x | x | 0 | m |
| 1.4.02 | Moveability | | | | | | | | |
| | 1.4.02.01 ease of operation folding/disassembly | m | m | m | m | m | m | m | m |
| | 1.04.02.02 ease of moving | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.4.03 | Manoeuvrability | | | | | | | | |
| | 1.4.03.02 turning radius/diagonal | x | 0 | 0 | x | 0 | 0 | x | x |
| | 1.4.03.03 turning radius/diagonal | m | x | x | 0 | x | x | 0 | m |
| 1.4.04 | Use on top of toilet | | | | | | | | |
| | 1.4.04.02 overlap toilet opening | 0 | m | m | m | m | m | m | m |

| | | | | | | | | | |
|---------------|---|----------|-----------|-----------|----------|------------|------------|-----------|-----------|
| 2 | TECHNICAL | | | | | | | | |
| 2.1 | <u>STRENGTH AND DURABILITY</u> | | | | | | | | |
| 2.1.01 | Strength | 7 | 8a | 8b | 9 | 11a | 11b | 12 | 14 |
| | 2.1.01.01 static strength | x | x | x | x | x | x | x | x |
| | 2.1.01.02 impact strength | x | x | x | x | x | x | x | x |
| 2.1.02 | Durability | | | | | | | | |
| | 2.1.02.03 fixing of paint coating | x | x | x | x | x | x | x | x |
| | 2.1.02.04 corrosion resistance | x | x | x | x | x | x | x | x |
| 2.1.03 | Technical quality of construction | | | | | | | | |
| | 2.1.03.01 frame | x | x | x | x | x | x | x | x |
| | 2.1.03.02 wheels and wheel suspension | x | x | x | x | x | x | x | x |
| | 2.1.03.03 brakes | x | x | x | x | x | x | x | x |
| | 2.1.03.04 fixing of support elements | x | x | x | x | x | x | x | x |
| 2.2 | <u>SAFETY AND MAINTENANCE</u> | | | | | | | | |
| 2.2.01 | Safety | | | | | | | | |
| | 2.2.01.01.01 stability tipping, loaded | x | x | x | x | x | x | x | x |
| | 2.2.01.02 shifting resistance | x | x | x | x | x | x | x | x |
| | 2.2.01.03 maximum unevenness | x | x | x | x | x | x | x | x |
| | 2.2.01.06 protection against moving parts | x | x | x | x | x | x | x | x |
| | 2.2.01.07 sharp parts | x | x | x | x | x | x | x | x |
| 2.2.02 | Maintenance | | | | | | | | |
| | 2.2.02.02 accessibility for cleaning purposes | x | x | x | x | x | x | x | x |

8 Literature

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D'Imprimerie

Annex 1 Examples of detrimental usability

A shower aid is evidently (apparently, very clear and without doubt) not useful if e.g.:

- The risk for fingers of getting pinched (e.g. armrest on protective plate, when changing sitting position, during which parts come (too) close to each other, in case of inadequate space between operation handle and shower aid component etc.)
- a change of sitting position is realised in such a way that an unsafe situation occurs (e.g. too abruptly or unstable situation)
- small parts (knob on footplate e.g.) protective cover on brake, become loose or remain loose after disassembly of the shower aid (wing bolts, axles when removing wheels etc.) and may fall on the floor or get lost etc.
- the EI sitting position of the shower aid α - and ϕ -adjustment) has to be adjusted once again after using following reducing the dimensions of the shower aid.
- (rust) water remains in the internal part of the product following a corrosion test.

Annex 2 Medical Devices Directive Checklist to Essential Requirements

European legislation

The European Commission has published the Directive on Medical Aids. The essential requirements included in this directive also apply to aids and appliances for handicapped. Aids for showering must also satisfy these requirements to qualify for marketing within the EU.

Aids for showering manufacturers may indicate themselves that their products meet these requirements by affixing a CE approval mark to the product. This has taken effect on January 1 1995. As of June 14 1998, all aids for showering to be marketed in Europe must have this CE approval mark.

To be of service to manufacturers, the Homologation Directive D 01 will be provided with a so called checklist. This checklist indicates under which essential requirements the D 01 test requirement fall. For this purpose, use has been made of the current insight into the situation as regards the normalisation of the essential requirements. The checklist is not aimed at reaching an exhaustive cover of the essential requirements. Obviously, the manufacturer shall remain responsible for affixing the CE approval mark.

In the following table, the official text of the essential requirements of the Directive on Medical Aids has been included in the first column.

The second column indicates by means of an 'R' whether the essential requirement involved is relevant to aids for showering. If not, this column is marked with a 'N' .

The numbers of the related requirements of homologation directive D 01 are stated in column 3.

Checklist

R= relevant
N= not relevant

| Essential Requirements | | R | D 01 |
|------------------------|---|---|--------------|
| I. | <u>GENERAL REQUIREMENTS</u> | R | 0.1 |
| 1. | The device must be designed and manufactured in such a way that, when used under the conditions and for the purpose intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risk which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. | | |
| 2. | The solution adopted by the manufacturer for the design and construction of the device must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: <ul style="list-style-type: none"> - eliminate or reduce risks as far as possible (inherently safe design and construction); - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated; - inform users of the residual risks due to any shortcomings of the protection methods adopted. | R | 0.1 |
| 3. | The devices must achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a) as specified by the manufacturer. | R | 0.1 clusters |
| 4. | The characteristics and performances referred to in sections 1,2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. | R | 2.1.02 |
| 5. | The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transportation and storage taking account of the instructions and information provided by the manufacturer. | R | |

| | | | |
|------------------------|---|---|------------------|
| Essential Requirements | | R | D 01 |
| 6. | Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended. | R | 0.1 |
| II. | <u>REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION</u> | R | 2.1.02 2.2.02 |
| 7. | Chemical, physical and biological properties. | | |
| 7.1 | The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the "General requirements". Particular attention must be paid to: <ul style="list-style-type: none"> - the choice of materials used, particularly as regards toxicity and, where appropriate flammability; - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. | | |
| 7.2 | The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure. | R | |
| 7.3 | The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gasses with which they enter into contact during normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use. | R | 2.1.02 2.2.02 |
| 7.4 | Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medical product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC. | R | |
| 7.5 | The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. | R | |

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|------------------------|---|---|--------|
| Essential Requirements | | R | D 01 |
| 7.6 | The devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. | R | 0.1 |
| 8. 8.1 | Infection and bacterial contamination The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use. | R | 2.1.02 |
| 8.2 | Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. | N | |
| 8.3 | Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. | N | |
| 8.4 | Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method. | N | |
| 8.5 | Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions. | N | |
| 8.6 | Packaging systems for non-sterile devices must keep the product without deterioration in the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of bacterial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer. | N | |

| | | | |
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| Essential Requirements | | R | D 01 |
| 8.7 | The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. | N | |
| 9. | Construction and environmental properties If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction for use. | R | 0.2 1.4.04 |
| 9.2 | Devices must be designed and manufactured in such a way as to remove or minimise as far as possible: <ul style="list-style-type: none"> - the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features; - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration; - the risk of reciprocal interference with other devices normally used in the investigations or for treatment given; - risks arising where maintenance or calibration are not possible (as with implants) from ageing of the materials used or loss of accuracy of any measuring or control mechanism. | | 2.1.01 2.1.03 2.2.02 1.1.01 1.1.02 1.1.03 1.1.05 1.2.01 1.2.02 1.2.03 1.3.01 1.3.02 1.3.03 1.4.01 1.4.02 1.4.03 |
| 9.3 | Devices must be designed and manufactured in such a way as to minimise the risk of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances which could cause combustion. | N | |
| 10. | Devices with a measuring function | N | |
| 10.1 | Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer. | N | |
| 10.2 | The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device. | N | |

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|------------------------|---|---|------|
| Essential Requirements | | R | D 01 |
| 10.3 | The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC , as last amended by Directive 89/617/EEC. | N | |
| 11. | Protection against radiation | N | |
| 11.1 | General | | |
| 11.1.1 | Devices shall be designed and manufactured such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. | | |
| 11.2 | Intended radiation | N | |
| 11.2.1 | Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed an manufactured to ensure reproducibility and tolerance of relevant variable parameters. | | |
| 11.2.2 | Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual display and/or audible warnings of such emissions. | N | |
| 11.3 | Unintended radiation | N | |
| 11.3.1 | Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation must be reduced as far as possible. | | |
| 11.4 | Instructions | N | |
| 11.4.1 | The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. | | |

| Essential Requirements | | R | D 01 |
|------------------------|--|---|------|
| 11.5 | Ionising radiation | N | |
| 11.5.1 | Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking account of the intended uses. | | |
| 11.5.2 | Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user. | N | |
| 11.5.3 | Devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation. | N | |
| 12 | Requirements for medical devices connected to or equipped with an energy source | N | |
| 12.1 | Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks. | | |
| 12.2 | Devices where the safety of the patient depends on an internal power supply must be equipped with a means of determining the state of the power supply. | N | |
| 12.3 | Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure. | N | |
| 12.4 | Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. | N | |
| 12.5 | Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment. | N | |

| | | | |
|-----------------------|--|---|-------------------------|
| Essential Requirement | | R | D 01 |
| 12.6 | <p>Protection against electrical risks</p> <p>Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electronic shocks during normal use and in single fault condition, provided that the devices are installed correctly.</p> | N | |
| 12.7 | <p>Protection against mechanical and thermal risks</p> | | 0.1 2.1.01 2.2.01 |
| 12.7.1 | <p>The devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.</p> | | |
| 12.7.2 | <p>The devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generation by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.</p> | R | |
| 12.7.3 | <p>The devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risk arising from noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.</p> | N | |
| 12.7.4 | <p>The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimise all possible risks.</p> | N | |
| 12.7.5 | <p>Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.</p> | R | 0.1 |
| 12.8 | <p>Protection against the risks posed to the patient by energy supplies or substances.</p> | N | |
| 12.8.1 | <p>Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and the user.</p> | | |

| | | | |
|------------------------|---|---|------|
| Essential Requirements | | R | D 01 |
| 12.8.2 | <p>Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.</p> <p>Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.</p> | N | |
| 12.9 | <p>The function of the controls and indicators must be clearly specified on the devices.</p> <p>When a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.</p> | R | 0.2 |
| 13. 13.1 | <p>Information supplies by the manufacturer.</p> <p>Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential user. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.</p> <p>Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class II if they can be used completely safely without any such instructions.</p> | R | 0.2 |
| 13.2 | <p>Where appropriate this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.</p> | R | 0.2 |

| Essential Requirement | | R | D 01 |
|-----------------------|--|---|------|
| 13.3 | <p>The label must bear the following particulars:</p> <ul style="list-style-type: none"> a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or the instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14.2 or of the authorised representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate; b) the details strictly necessary for the user to identify the device and the contents of the packaging; c) where appropriate the word "Sterile"; d) where appropriate, the batch code, preceded by the word "Lot" or the serial number; e) where appropriate an indication of the date by which the device should be used, in safety, expressed as the year and month; f) where appropriate, an indication that the device is for single use; g) if the device is custom-made, the words "custom made device"; h) if the device is intended for clinical investigations, the word "exclusively for clinical investigation"; i) any special storage and/or handling conditions; j) any special operating instructions; k) any warnings and/or precautions to take; l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number; m) where applicable, method of sterilisation. | R | |
| 13.4 | <p>If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instruction leaflet.</p> | R | |
| 13.5 | <p>Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action detect any potential risk posed by the devices and detachable components.</p> | R | |

| Essential Requirement | | R | D 01 |
|-----------------------|--|---|------|
| 13.6 | <p>Where appropriate, the instructions for use must contain the following particulars:</p> <ul style="list-style-type: none"> a) the details referred to in 13.3, with the exception of d) and e); b) the performances referred to in section 3 and any undesirable side effects; c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; e) where appropriate, information to avoid certain risks in connection with implantation of the device; f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation; h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the device to be re-sterilised, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilised before use, the instructions for cleaning and sterilisation must be such that, if correctly followed, the device will still comply with the requirements in section 1; i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.); j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. <p>The instruction for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken.</p> | R | |

| Essential Requirement | | R | D 01 |
|-----------------------|---|---|------|
| | <p>These details should cover in particular:</p> <ul style="list-style-type: none"> k) precautions to be taken in the event of change in the performance of the device; l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharges, pressure or fluctuation of pressure, acceleration, thermic sources of ignition, etc.; m) adequate information regarding the medicinal products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered.; n) precautions to be taken against any special unusual risk related to the disposal of the device; o) medicinal substances incorporated into the device as an integral part in accordance with section 7.4; p) degree of accuracy claimed for devices with measuring function. | | |
| 14. | When conformity with the essential requirements must be based on clinical data, as in section I (6), such data must be established in accordance with Annex X. | N | |

Annex 3 Alphabetical list of all properties

| | |
|---|----|
| Accessibility for cleaning purposes | 32 |
| Adjustment of angle ϕ (transfer angle) attendant | 26 |
| Adjustment of angle ϕ (transfer angle) user | 25 |
| Angle α | 25 |
| Backrest height | 26 |
| Brakes | 31 |
| Care height | 27 |
| Corrosion Sensitivity | 31 |
| Displacement resistance | 32 |
| Ease of moving | 30 |
| Ease of operation braking system, attendant | 30 |
| Ease of operation braking system, user | 29 |
| Ease of operation reducing size/disassembly | 30 |
| Fixing of lake | 31 |
| Fixing of support elements | 32 |
| Foot support design | 27 |
| Frame | 31 |
| Get up height | 29 |
| Get up space | 27 |
| Impact resistance | 31 |
| Lower leg support | 26 |
| Manoeuvring force | 29 |
| Maximum unevenness | 32 |
| Overlap toilet opening | 30 |
| Product Information | 24 |

| | |
|----------------------------------|----|
| Protection of moving parts | 32 |
| Removing of armrest, attendant | 28 |
| Removing of armrest, user | 27 |
| Removing foot/legrest, attendant | 28 |
| Removing foot/legrest, user | 28 |
| Removing/placing bed pan | 27 |
| Seat depth | 26 |
| Seat height | 26 |
| Seat width | 26 |
| Self-propelling (hand) | 29 |
| Self-propelling (leg) | 29 |
| Sharp parts | 32 |
| Shift over depth | 27 |
| Shift over distance | 27 |
| Shift over height | 27 |
| Stability of tipping, loaded | 32 |
| Static strength | 31 |
| Surface | 30 |
| Total shower aid | 24 |
| Transfer angle ϕ | 25 |
| Transfer height | 29 |
| Tripping height | 29 |
| Tripping space | 29 |
| Turning circle/diagonal | 30 |
| Wedge angle α | 25 |
| Wheel and wheel suspension | 31 |