

Specifications for stretchers and other patient handling equipment used in road ambulances

The European Standard EN 1865:1999 has the status of a
British Standard

ICS 11.160

National foreword

This British Standard is the English language version of EN 1865:1999.

The UK participation in its preparation was entrusted to Technical Committee CH/116, Rescue Systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Summary of pages

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English version

Specifications for stretchers and other patient handling
equipment used in road ambulances

Spécifications des brancards et équipements d'ambulances
pour le transport des patients

Festlegungen für Krankentragen und andere
Krankentransportmittel im Krankenwagen

This European Standard was approved by CEN on 8 August 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 239 "Rescue systems", the Secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard with the general title "Specifications for stretchers and other patient handling equipment used in road ambulances" incorporates specifications for:

- Main stretcher – undercarriage
- Chair stretcher
- Transfer mattress
- Carrying sheet
- Pick up stretcher
- Vacuum mattress and pump
- Long spinal board
- Foldable carrying chair
- Non-foldable carrying chair

This European Standard is closely related to prEN 1789 "Medical vehicles and their equipment - Road ambulances".

NOTE: Standardization work will continue with the aim of ensuring the safe transfer of patients and equipment without compromising continuity of patient care and the safety of staff.

1 Scope

This European Standard defines minimum requirements for the design and performance of stretchers and other patients handling equipment used in road ambulances for handling and carrying a patient in such a way that supplementary injuries due to handling are reduced to a minimum.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 292-2

Safety of machinery - Basic concepts, general principles for design – Part 2: Technical principles and specifications

EN 597-1

Furniture – Assessment of the ignitability of mattresses and upholstered bed bases – Part 1: Ignition source: Smouldering cigarette

EN 980

Graphical symbols for use in the labelling of medical devices

EN 1021-1

Furniture - Assessment of the ignitability of upholstered furniture – Part 1: Ignition source: Smouldering cigarette (ISO 8191-1:1987, modified)

EN 1041

Information supplied by the manufacturer with medical devices

prEN 1789:1999

Medical vehicles and their equipment – Road ambulances

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 Main stretcher

The main means for the conveyance of sick and/or injured persons in transit in a recumbent position in safety and in comfort whilst facilitating treatment.

3.2 Chair stretcher

A device designed to handle and carry a patient in a sitting or lying position, including conveying a patient in the vehicle.

3.3 Transfer mattress

A device intended to facilitate the transfer of the patient from one stretcher to another.

3.4 Carrying sheet

A special sheet to handle and carry a patient in a lying or sitting position.

3.5 Pick up stretcher

A lifting device, intended to be used for movement of seriously injured people on to other transport devices.

3.6 Vacuum mattress

A device intended primarily to provide whole body immobilization during the transportation of the patient.

3.7 Long spinal board

A device to lift and immobilize patients with spinal injuries.

3.8 Foldable carrying chair

A device intended to handle and carry a patient in a sitting position to the road ambulance but not to be used to transport a patient within the ambulance.

3.9 Non-foldable carrying chair

A device intended to handle and carry a patient in a sitting position to the road ambulance and to be used to transport a patient within the ambulance.

4 Requirements

All equipment for handling of patients shall guarantee a safe and smooth manipulation.

All equipment for handling of patients shall be secured so that any movement during ambulance transport is prevented, even in bad transport conditions.

Carrying handles of devices for handling of patients shall permit fixation in extended positions.

All equipment for handling of patients shall be free of any sharp edges or deformation that could cause damage to persons or other equipment on board.

For all patients transported in the patients compartment, patient restraint-systems shall be available.

All patient restraint-systems shall have a quick release system.

The patient restraint-system for all patient handling equipment shall immobilize the patient, but at the same time shall permit treatment of the patient.

The lying-sitting part shall be made of a strong material which is bacterial resistant, fungal resistant, stain resistant, putrid resistant, easy to clean, washable, waterproof and petrol-oil resistant.

4.1 Main stretcher

4.1.1 General

The main stretcher shall consist of a stretcher part that can be used alone or in combination with an integrated or separable undercarriage.

It shall be designed to provide that the full weight of the patient and the carried stretcher part will only be lifted/carried by the personnel for the minimum period of time.

It shall be designed to provide that during loading and unloading the maximum burden on any personnel is half of the total weight of patient and stretcher and for the minimum possible time and in an optimal ergonomic position so that back bending is minimized.

4.1.2 Dimensions

Dimensions shall be measured from the outermost edges.

| | | | |
|-----------------|---|---|--|
| Stretcher part: | length: | (1 950 ⁺²⁰ ₋₅₀ mm | maximum 300 mm from loading holding assembly to unladed lying part. This height dimensions does not apply to stretchers with monoblock undercarriages. If a monoblock is not available, the stretcher must be constructed so that it is detachable from the undercarriage. |
| | width: | (500 ± 20) mm | |
| | height: | | |
| Undercarriage: | length and width of the frame of the undercarriage in car position shall not exceed length and width of the stretcher part. | | |

4.1.3 Mass

The mass excluding mattress and patient restraints shall be not more than

| | |
|---|-------|
| Stretcher part: | 23 kg |
| Undercarriage: | 28 kg |
| Stretcher part with integrated undercarriage: monoblock | 45 kg |

NOTE: In all cases the mass should be as low as possible.

4.1.4 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.1.5 Frame

The frame shall be in sturdy lightweight non twisting construction enabling use of cardiopulmonary resuscitation. All corners of the frame shall be radiused for greater safety.

It shall be possible to lock and secure the stretcher and undercarriage against lateral, longitudinal, vertical and oblique movements.

All mechanisms shall be constructed to prevent damage to the user and the patient.

4.1.5.1 Stretcher parts

- a) If swing down siderails are mounted, they shall have a minimum length of 500 mm and a height between 150 mm and 200 mm.
- b) If longitudinal handles are incorporated they shall be fitted to the ends of the longitudinal frame such that they lock and do not twist when they are stowed or in use. They shall be designed to minimize the risk of injuries to the hands and wrists when the stretcher is carried at angles. It shall allow the fixation and use of a carrying harness and yoke.
- c) There shall be a facility to attach a support for infusion.
- d) The longitudinal bars shall be connected together such that torsion is avoided.
- e) The stretcher shall have either a water and scratch resistant paint finish or be manufactured of corrosion resistant material. Both versions shall be unaffected by disinfectants.
- f) If intended to be used without undercarriage there shall be 4 wheels with a minimum diameter of 100 mm suitably placed to ensure stability.
- g) If intended to be used with undercarriage the stretcher shall be able to be fixed to the undercarriage without using supplementary means. A safe handling and lowering of the undercarriage shall be ensured.
- h) The fixed stretcher shall be easy to release from the stretcher tray or the undercarriage.

4.1.5.2 Undercarriage

- a) The undercarriage shall be fitted with 4 wheels with a diameter of at least 100 mm. There shall be a minimum of two 360 degrees swivel wheels at the foot end and at least two wheels shall be fitted with a footbrake.
- b) The undercarriage shall be suitable for a road ambulance loading and unloading height of maximum 750 mm.
- c) The undercarriage shall have a simple mechanism for height adjustment and shall have a minimum of two levels (car position and fully unfolded).
- d) The supporting mechanism shall automatically stay in place when fully unfolded.
- e) The operating controls shall be designed in accordance with the body dimensions, physical strength and anatomical and physiological requirements of human beings. The operating controls shall be clearly and permanently labelled, preferably with graphical symbols, indicating their positions and settings. If the controls can initiate movements which could be dangerous to persons, they shall be secured against unintentional operation.
- f) All the functions of the stretcher shall remain completely unimpaired when it is connected to the undercarriage.
- g) The undercarriage shall either be provided with a waterproof and scratch resistant finish or be made of corrosive resistant material or similar surface.
- h) If the undercarriage is used with a separable stretcher it shall be possible both to connect the undercarriage to the stretcher and to separate them easily. The mounting for the stretcher shall be secured in such a manner that unintentional separation of undercarriage and stretcher cannot occur. It shall be possible to load and unload the undercarriage and stretcher so as to ensure the safety and comfort of the patient and the operators.

4.1.6 Lying part of the stretcher

- a) The lying area shall be flat over the complete surface and shall be made of sturdy lightweight construction. The thorax area shall be manufactured of sturdy lightweight material which allows cardiopulmonary resuscitation without acting as a spring or giving way. The materials shall be unaffected by disinfectants.

b) The lying area shall be non-slip and shall be covered with a transfer mattress, or a mattress that shall provide for patient comfort and also be firm enough to enable cardiopulmonary resuscitation to be undertaken. The mattress shall be able to conform to the various treatment configuration provided by the stretcher.

c) The lying area shall have an adjustable head-end/backrest with a minimum length of 600 mm. It shall be possible to turn up the backrest at least 75 degrees and there shall be at least five fixing positions within this range. It shall be possible to maintain the angle of adjustment under all normal cases of loading and unloading.

d) The lying area shall have an adjustable footrest with a minimum length of 900 mm. It shall be possible to turn up the footrest at least 15 degrees. It shall be possible to maintain the angle of adjustment under all normal cases of loading and unloading.

4.1.7 Restraint system

The stretcher shall have a minimum of two quick-release patients restraints.

4.1.8 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.1.9 Deformation of the frame

The frame shall not bend or break when tested in accordance with 5.1.1.

4.1.10 Fixation

The requirement of the fixation shall be in accordance with 4.5.9 of prEN 1789:1999. There shall be no deformation of the fixation when tested in accordance with 5.1.2.

4.1.11 Deformation of the lying area

There shall be no deformation of the lying area when tested in accordance with 5.1.3.

4.1.12 Resistance to torsion

There shall be no remaining deformation to torsion when tested in accordance with 5.1.4.

4.1.13 Splaying of the wheels

The wheels shall not splay more than 2 mm in total during the test specified in 5.1.5 and there shall be no permanent deformation.

4.2 Chair stretcher

4.2.1 Dimensions

The dimensions of the chair stretcher shall be as follows:

| | |
|---------|-----------------|
| Length: | (1 900 ± 50) mm |
| Width: | (550 ± 30) mm |

4.2.2 Mass

The mass shall be not more than 23 kg.

NOTE: The mass should be as low as possible.

4.2.3 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.2.4 Frame

The frame of the chair stretcher shall be made of a sturdy lightweight construction and shall be able to be locked in the chair-position. The chair stretcher shall have at least two rear wheels.

4.2.5 Lying-sitting part

The lying-sitting part shall be made of a strong material which is bacterial resistant, fungal resistant, stain resistant, putrid resistant, easy to clean, washable, waterproof and petrol-oil resistant.

4.2.6 Restraint system

There shall be at least two quick release patient restraints.

4.2.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.2.8 Deformation of the frame

The frame of the chair stretcher shall not open spontaneously or bend when tested in accordance with 5.2.1.

4.2.9 Fixation

Not applicable.

4.2.10 Deformation of the lying-sitting area

There shall be no remaining deformation of the lying-sitting area when tested in accordance with 5.2.2.

4.2.11 Resistance to torsion

There shall be no remaining deformation to torsion when tested in accordance with 5.2.3.

4.2.12 Splaying of the wheels

The wheels shall not splay more than 2 mm in total during the test specified in 5.2.4 and there shall be no permanent deformation.

4.3 Transfer mattress

4.3.1 Dimensions

The dimensions of the transfer mattress of the lying area shall be as follows:

| | |
|---------|----------------------------|
| Length: | (1 950 $^{+20}_{-50}$) mm |
| Width: | maximum 500 mm |
| Height: | maximum 100 mm |

4.3.2 Mass

The mass shall be not more than 10 kg.

NOTE: The mass should be as low as possible.

4.3.3 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.3.4 Handles

The transfer mattress shall be equipped with at least 4 handles on each longitudinal side, the handles shall be designed to give a comfortable and safe grip.

4.3.5 Lying part

Both sides of the transfer mattress shall have a different function: one side shall provide a lying comfort equivalent to a foam filling of minimum 40 mm with density 30 to 40 kg/m³, the other side shall provide the mattress with sufficient rigidity to transfer the patient with at least 2 persons, one at each longitudinal side.

The mattress shall be capable of being adopted to the form of the lying part of the stretcher.

The lying part shall be constructed in such a way that prevents the ingress of fluids. The material shall be easy to clean, washable, petrol-oil resistant and allow preliminary x-ray diagnostics. It shall withstand temperatures ranging from + 70 °C to - 30 °C.

4.3.6 Restraint system

Not applicable.

4.3.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.3.8 Deformation

There shall be no remaining deformation of the mattress when tested in accordance with 5.3.1.

4.3.9 Fixation

Not applicable.

4.3.10 Deformation of the lying area

There shall be no remaining deformation of the lying area when tested in accordance with 5.3.2.

4.3.11 Resistance to torsion

Not applicable.

4.3.12 Splaying of the wheels

Not applicable.

4.4 Carrying sheet

4.4.1 Dimensions

The dimensions of the carrying sheet shall be as follows:

| | | |
|---------|---------|----------|
| Length: | minimum | 1 850 mm |
| Width: | minimum | 570 mm |

4.4.2 Mass

The mass shall be not more than 5 kg.

NOTE: The mass should be as low as possible.

4.4.3 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.4.4 Handles

The carrying sheet shall be equipped with at least 3 handles on each longitudinal side.

4.4.5 Lying part

The lying part of the carrying sheet shall be made of a strong material which is bacterial resistant, fungal resistant, washable, disinfectable, putrid resistant, waterproof, petrol-oil resistant and allow preliminary x-ray diagnostics.

4.4.6 Restraint system

Not applicable.

4.4.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.4.8 Deformation of the handles

There shall be no remaining deformation of the handles when tested in accordance with 5.4.1.

4.4.9 Fixation

Not applicable.

4.4.10 Deformation of the lying area

There shall be no remaining deformation of the lying area when tested in accordance with 5.4.2.

4.4.11 Resistance to torsion

Not applicable.

4.4.12 Splaying of the wheels

Not applicable.

4.5 Pick up stretcher

4.5.1 Dimensions

The dimensions of the pick up stretcher shall be as follows:

The usable length shall be a minimum of 1650 mm and extendable to a minimum of 2010 mm.

| | | |
|-------------------|---------|---------|
| Width: | minimum | 400 mm |
| Thickness folded: | maximum | 90 mm |
| Length folded: | maximum | 1200 mm |

4.5.2 Mass

The mass shall be not more than 11 kg.

NOTE: The mass should be as low as possible.

4.5.3 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.5.4 Frame

The frame of the pick up stretcher shall be made of a sturdy lightweight construction with built-in handholds.

It shall be adjustable lengthways to accommodate all sizes of patients. It shall be constructed so that the two parts can be separated and closed in normal use.

4.5.5 Lying part

The surfaces shall be concave to cradle the patient so as to provide support and minimize lateral movement. The concave surfaces shall be fixed rigidly to the frame. Joints, openings and seals shall be sealed.

4.5.6 Restraint system

There shall be three quick-release patient restraints.

4.5.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.5.8 Deformation of the frame

The frame of the pick up stretcher shall not bend or break when tested in accordance with 5.5.1.

4.5.9 Locking

The hinges and bolts shall not open spontaneously or bend when tested in accordance with 5.1.2.

4.5.10 Deformation of the lying area

There shall be no remaining deformation of the lying area when tested in accordance with 5.1.3.

4.5.11 Resistance to torsion

There shall be no remaining deformation when tested in accordance with 5.5.2.

4.5.12 Splaying of the wheels

Not applicable.

4.6 Vacuum mattress

4.6.1 General

The mattress shall be made of strong material which is disinfectable, washable, putrid resistant, waterproof, petrol-oil resistant and allows preliminary x-ray diagnostics. The valve, neither the air inlets nor outlets shall disturb the patient.

The pump shall be able to reduce the pressure by 500 hPa within 4 min.

The vacuum mattress including the filling shall have the following minimum properties:

- | | |
|---|----------------|
| – heat resistance: | 70 °C |
| – heat resistance pre-loaded with 5000 N/m ² : | 50 °C |
| – cold resistance: | - 30 °C |
| – melting point: | approx. 100 °C |

4.6.2 Dimensions

The dimensions of the vacuum mattress shall be as follows:

| | | | |
|---------|---------|---------|--------------------------------|
| Length: | minimum | 2000 mm | |
| Width: | minimum | 800 mm | in flat position ¹⁾ |

4.6.3 Mass

The mass including the pump shall be not more than 15 kg.

NOTE: The mass should be as low as possible.

4.6.4 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.6.5 Handles

The vacuum mattress shall be equipped with at least 4 handles on each longitudinal side, in order to be able to transport a patient in an immobilized position.

4.6.6 Restraint system

During transportation the mattress shall be in accordance with 4.5.9 of prEN 1789:1999.

When a patient is being conveyed outside of the vehicle or craft, a system shall be available to ensure that the patient can be carried in a safe manner.

4.6.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 597-1.

4.6.8 Deformation

There shall be no permanent deformation when tested in accordance with 5.6.1.

4.6.9 Shrinkage

The immobilization of the patient is achieved by the suitable shrinkage of the vacuum mattress. In order to avoid additional injuries the shrinkage shall not exceed the following requirement. The shrinkage of the lying area of the mattress shall not be more than 1 % in length and 3 % in width when tested in accordance with 5.6.2.

4.6.10 Deformation of the lying area

There shall be no remaining deformation of the lying area when tested in accordance with 5.6.3.

4.7 Long spinal board

4.7.1 Dimensions

The dimensions of the long spinal board shall be as follows:

The usable length shall be a minimum of 1 830 mm and a maximum of 1 980 mm.

| | | |
|--------|----------------|-----------------------|
| Width: | minimum 400 mm | maximum 500 mm |
| Depth: | maximum 70 mm | (unfolded and folded) |

¹⁾ A greater width should be aimed at.

4.7.2 Mass

The mass shall be not more than 8 kg.

NOTE: The mass should be as low as possible.

4.7.3 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.7.4 Construction

The long spinal board shall be of a sturdy lightweight construction. It shall be equipped with a minimum of 3 handholds on each longitudinal side and a minimum of 2 handholds at both the foot and head ends.

The handles shall be easily accessible and give a safe grip for lifting or lowering and carrying the board.

4.7.5 Lying part

The lying part shall be designed so that it will give maximum support for the head and whole torso.

The lying part shall be designed in such a way that it prevents the ingress of fluids. The material shall be easy to clean, washable, petrol-oil resistant and allow preliminary x-ray diagnostics. It shall withstand temperatures ranging from + 70 °C to - 30 °C.

4.7.6 Restraint system

There shall be three quick-release patient restraints.

4.7.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.7.8 Deformation

Not applicable.

4.7.9 Fixation

Not applicable.

4.7.10 Deformation of the lying area

The spinal board shall not bend permanently or break, when tested in accordance with 5.7.1.

4.7.11 Resistance to torsion

There shall be no remaining deformation, when tested in accordance with 5.7.2.

4.7.12 Splaying of the wheels

Not applicable.

4.8 Foldable carrying chair

4.8.1 Dimensions

The dimensions of the foldable carrying chair shall be as follows in open position:

| | | |
|---------------|---------------------|----------------------------------|
| The seat: | – minimum height | 300 mm, measured from the ground |
| | – maximum height of | 500 mm, measured from the ground |
| | – minimum width | 330 mm |
| | – minimum depth | 350 mm |
| The backrest: | – minimum height | 395 mm, measured from the seat |
| | – minimum width | 300 mm |

4.8.2 Mass

The mass shall be not more than 10 kg.

NOTE: The mass should be as low as possible.

4.8.3 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.8.4 Frame

The frame of the foldable carrying chair shall be made of sturdy lightweight construction. It shall be furnished with 2 non-slip carrying handles on the foot-bar, and 2 non-slip handles on the top-frame. It also shall have a footrest and a minimum of two wheels of a diameter 100 mm minimum at the rear.

It shall be able to store the carrying chair in a folded position.

4.8.5 Sitting part

The backrest and the sitting part shall be made of strong material which is bacterial resistant, fungal resistant, stain resistant, putrid resistant, easy to clean, washable, waterproof, petrol-oil resistant.

4.8.6 Restraint system

There shall be at least two quick-release patient restraints.

4.8.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.8.8 Deformation of the frame

There shall be no remaining deformation of the frame when tested in accordance with 5.8.1.

4.8.9 Locking

The hinges and bolts shall not open spontaneously or bend.

4.8.10 Deformation of the backrest lying-sitting area

There shall be no remaining deformation of the back-rest and lying-sitting area, when tested in accordance with 5.8.1.

4.8.11 Resistance to torsion

Not applicable.

4.8.12 Splaying of the wheels

Not applicable.

4.9 Non-foldable carrying chair (sedan chair)

4.9.1 Dimensions

The dimensions of the non-foldable carrying chair shall be as follows:

| | | |
|---------|---------|---|
| Height: | Maximum | 1 250 mm |
| Width: | Maximum | 600 mm |
| Length: | Maximum | 950 mm with carrying handles folded |
| | Maximum | 1 650 mm with carrying handles extended |

4.9.2 Mass

The mass shall be not more than 22 kg.

NOTE: The mass shall be as low as possible.

4.9.3 Loading capacity

The loading capacity shall be a minimum of 150 kg.

4.9.4 Frame

The frame of the non-foldable carrying chair shall be of a sturdy lightweight non-twisting construction. It shall have four wheels of at least 100 mm diameter. Either the front or rear wheels shall be able to swivel through 360 degrees. If all four wheels are able to swivel through 360 degrees, at least two shall be lockable when the non-foldable carrying chair moves straight ahead.

The frame shall be provided with telescopic or equivalent foldable carrying handles at footend and backrest and shall have upholstered armrests and foldable footrest(s).

4.9.5 Sitting part

The non-foldable carrying chair shall have a comfortable seat and backrest mattress with integrated headrest.

It shall be made of strong material which is bacterial resistant, fungal resistant, stain-resistant, putrid resistant, easy to clean, washable, waterproof, petrol-oil resistant.

4.9.6 Restraint system

There shall be two quick release patient restraints.

4.9.7 Flammability – toxicity burning gases

There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 1021-1.

4.9.8 Deformation of the frame

There shall be no remaining deformation of the frame of the non-foldable carrying chair when tested in accordance with 5.9.1

4.9.9 Fixation

The hinges and bolts shall not open spontaneously or bend when tested in accordance with 5.9.2. The requirement of the fixation shall be in accordance with 4.5.9 in prEN 1789:1999.

4.9.10 Deformation of the sitting area

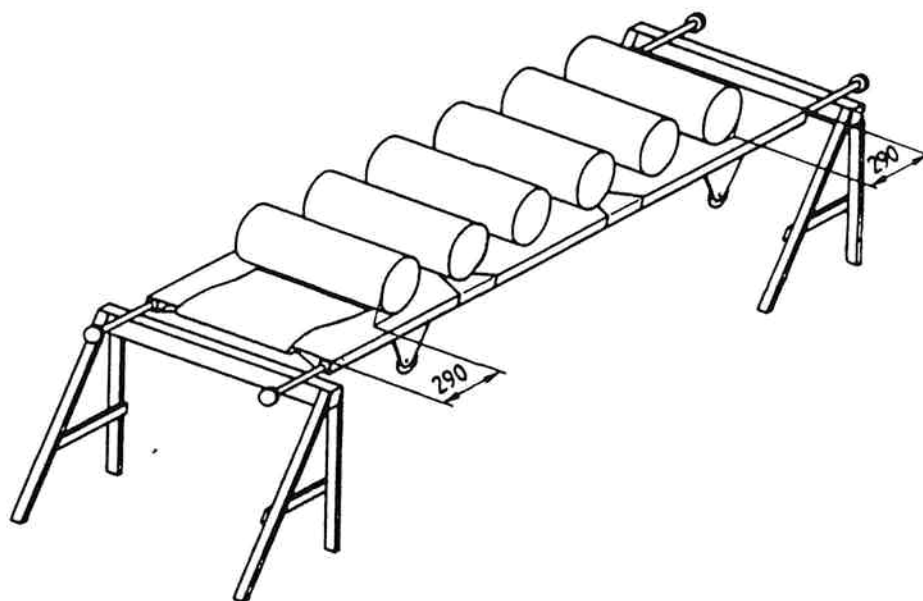


Figure 1

There shall be no remaining deformation of the backrest and sitting area when tested in accordance with 5.9.1.

4.9.11 Resistance to torsion

Not applicable.

4.9.12 Splaying of the wheels

There shall be not more than 2 mm of splaying of the wheels when tested in accordance with 5.9.3.

5 Test methods

5.1 Main stretcher

5.1.1 Permanent deformation of the frame

5.1.1.1 Stretcher frame

For the test of permanent deformation (bending), the stretcher shall be positioned with the handles completely pulled out. During the test, the frame/undercarriage shall stand on a flat inflexible ground.

The stretcher shall be loaded evenly with 250 kg (e.g. with 6 sandbags) according to figure 1. The sandbags shall not rest on the longitudinal bars.

Unload the stretcher and examine for deflections and/or failures.

5.1.1.2 Undercarriage frame

The undercarriage with stretcher shall be subject to an evenly-distributed load of 250 kg and pushed at a maximum speed of 4 km/h for a distance of 100 m on a hard, horizontal surface, the unevenness of which may be equivalent to 2,5 % of the wheel diameter.

Following this test, the undercarriage with stretcher bearing the 250 kg load shall be moved so that one wheel collides frontally with a 100 mm high, vertical and rigid obstacle at a speed of 4 km/h.

Unload and examine for deflections and/or failures.

5.1.2 Fixation inside the ambulance

The requirement of the fixation shall be in accordance with 4.5.9 of prEN 1789:1999.

5.1.3 Permanent deformation of the lying area

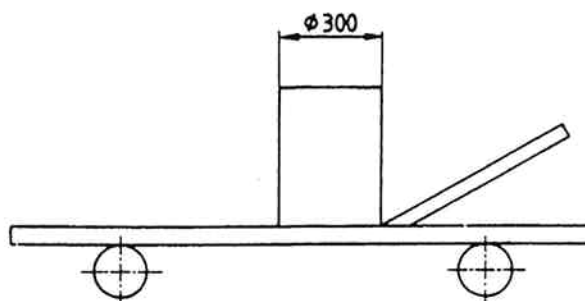


Figure 2

For the test of permanent deformation the stretcher shall be loaded with a sandbag of 150 kg according to figure 2.

Unload the lying area and examine for deflection and/or failures. There shall be no remaining deformation or defects.

5.1.4 Resistance to twisting/torsion

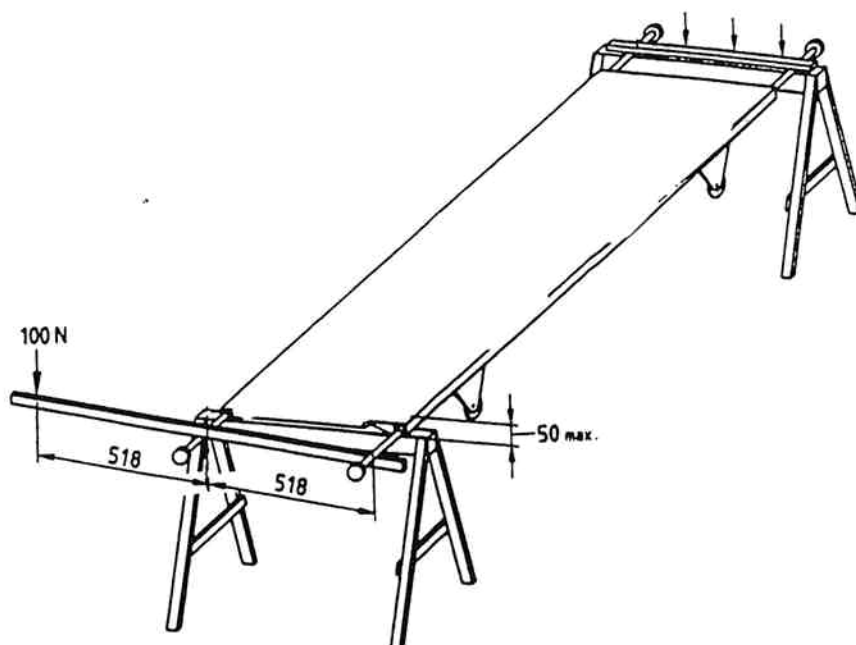


Figure 3

To run the test on resistance against torsion the non-loaded stretcher shall be fixed at one end in the middle of the completely pulled out handles, on the other side the longitudinal bars shall be laid on a test stand. At this free end a lever shall be fitted out to the pulled out handles. The lever shall be loaded with 100 N according to figure 3.

The longitudinal bar shall lift itself from the surface of the test stand by max. 50 mm, measured from the upper edge of the test stand to the lower edge of the longitudinal bar. No remaining deformation shall occur.

5.1.5 Splaying of the wheels

To run the splaying test of the wheels the stretcher/undercarriage shall be placed on a flat plane and moved forward and backward 500 mm each. The stretcher is loaded evenly with 250 kg (e.g. with 6 sandbags).

5.2 Chair stretcher

5.2.1 Permanent deformation of the frame

Secure chair handles on support. Suspend chair stretcher by the handles as if the chair stretcher was being carried. Secure chair stretcher handles to the supports with restraint straps to prevent the handles from sliding off the supports.

Load the chair with 250 kg distributing the weight in the chair stretcher much as a patient's weight would be distributed.

Unload chair stretcher and examine for deflections and/or failures. There shall be no remaining deformation or defects.

5.2.2 Permanent deformation of the lying-sitting area

The test of the chair stretcher in reclined position shall be in accordance with 5.1.3.

5.2.3 Resistance to twisting/torsion

Idem as for the main stretcher (see 5.1.4).

5.2.4 Splaying of the wheels

Load the chair stretcher in chair position with 250 kg. Tip chair back on wheels as if transporting a patient and roll the chair over smooth surfaces, door-sills, minor obstructions, and any other types of surfaces that might be expected during intended use.

Unload chair stretcher and examine for deflections an/or failures. There shall be no remaining deformation or defects.

5.3 Transfer mattress

5.3.1 Deformation

The transfer mattress is subject to static tests in accordance with figure 4 and 5. Apply a force of $F = 2\,500\text{ N}$ between all opposite carrying loops as shown in example in figure 4 for the middle loops.

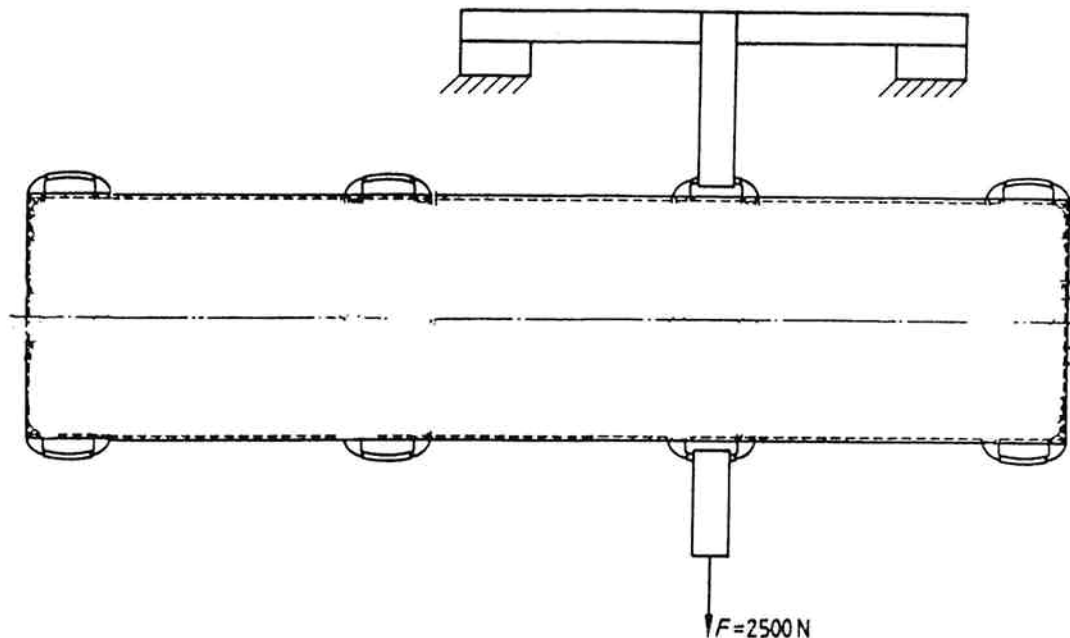


Figure 4

Apply a force of $F = 1\,000\text{ N}$ between the outer and middle loops of each side as shown in figure 5.

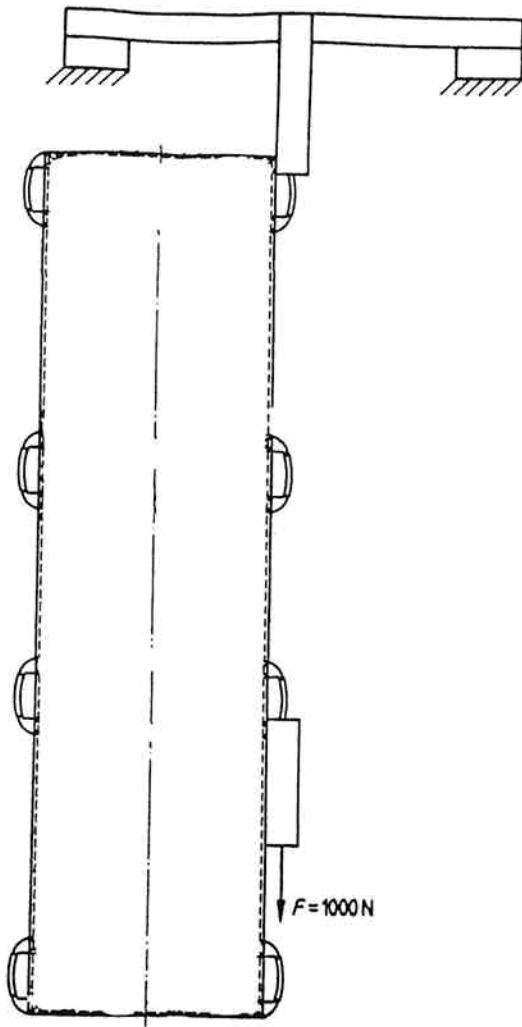


Figure 5

There shall be no broken threads upon completion of the above test.

5.3.2 Deformation of the lying area

Secure the transfer mattress handles, along the length of the transfer mattress, to support. Transfer mattress will be suspended from the supports.

Load transfer mattress with 250 kg, distributing the weight evenly along the length of the transfer mattress. Unload mattress and examine for failures. There shall be no remaining deformation or defects.

5.4 Carrying sheet

5.4.1 Strength of the handles

The carrying sheet is subject to static tests in accordance with figure 6 and 7.

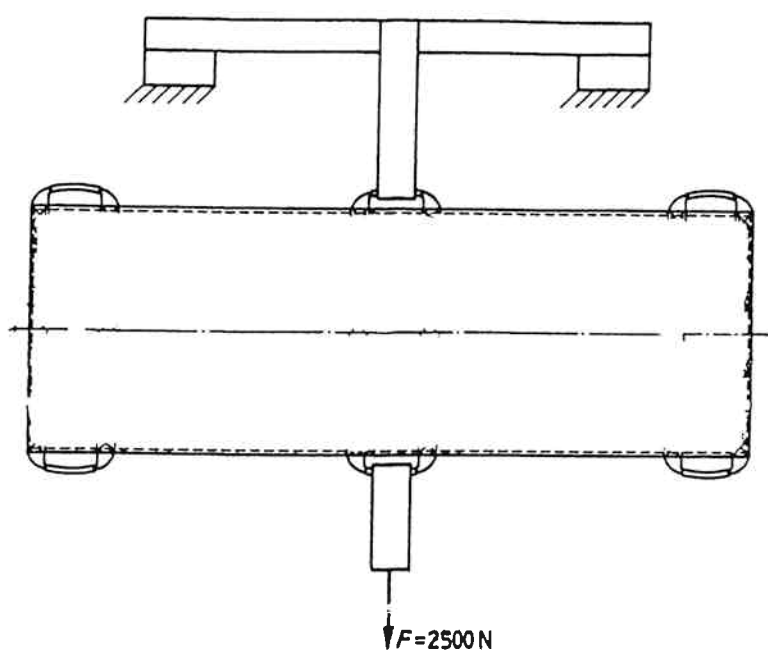


Figure 6

- a) Apply a force of $F = 2\,500\text{ N}$ between all opposite carrying handles as shown in example in figure 6 for the middle handles.
- b) Apply a force of $F = 1\,000\text{ N}$ between the outer and middle handles of each side as shown in figure 7.

There shall be no broken threads upon completion of the above tests.

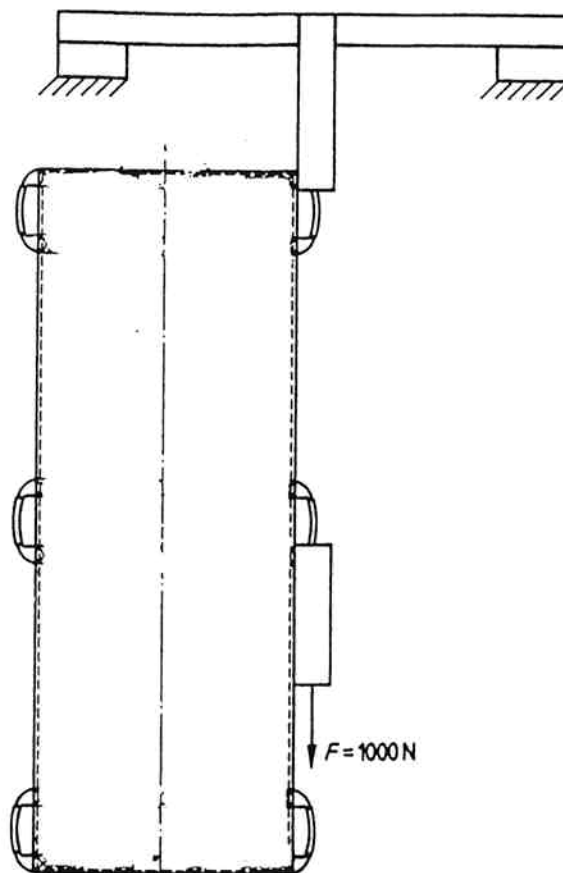


Figure 7

5.4.2 Permanent deformation of the lying area

Secure carrying sheet handles, along the length of the carrying sheet, to support. Carrying sheet will be suspended from the supports.

Load carrying sheet with 250 kg, distributing the weight evenly along the length of the carrying sheet. Unload sheet and examine for failures. There shall be no remaining deformation or defects.

5.5 Pick up stretcher

5.5.1 Permanent deformation of the frame

Place fully extended stretcher on supports positioned 300 mm from the ends of the stretcher. Load stretcher with 250 kg, distributing the weight evenly along the length of the stretcher.

Unload stretcher and examine for deflections and/or failures by telescoping the frame in and out and operating end latches and pin locks. There shall be no remaining deformation or defects.

5.5.2 Resistance to twisting/torsion

Idem as for the main stretcher (see 5.1.4).

5.6 Vacuum mattress and pump

5.6.1 Deformation

For rigidity and density the mattress shall be placed on a stand:

- the pressure inside the vacuum mattress shall be reduced by 500 hPa;
- after 30 min, the remaining pressure difference shall be at least 300 hPa;
- the mattress (after opening the valve) shall be shaped to a human body by means of a test person of (75 ± 5) kg body weight, and a height of (175 ± 5) cm;
- the pressure inside the vacuum mattress shall be reduced again by 500 hPa;

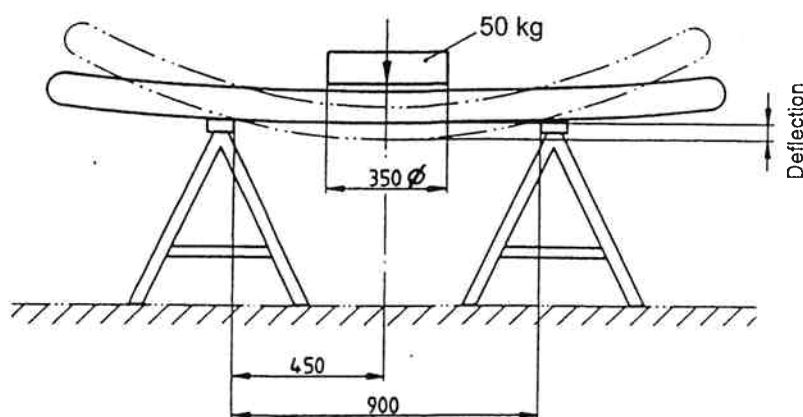


Figure 8

- the test person shall be removed;
- the mattress is then placed according to figure 8 with a load of 50 kg applied on a surface of 350 mm diameter centred in the middle of the mattress;
- after 2 hours the remaining pressure difference shall be at least 300 hPa and the deflection shall not exceed 100 mm.

5.6.2 Shrinkage

Place the mattress in flat position on a flat surface. Measure the mattress in the middle longitudinally and middle transversally. The pressure inside the mattress shall then be reduced by 500 hPa. Measure the size of the mattress, at same places as before, whilst under this vacuum pressure.

5.6.3 Deformation of the lying area

- The pressure inside the vacuum mattress shall be reduced by 500 hPa and then suspended by means of its external handles (instead of loops) and a load of 250 kg applied as shown in figure 9;
- after 15 minutes there shall be no visible damage and/or failure;
- the same applies if the mattress is provided with a protective coating/cover and if the latter is intended to be used in combination with the patient.

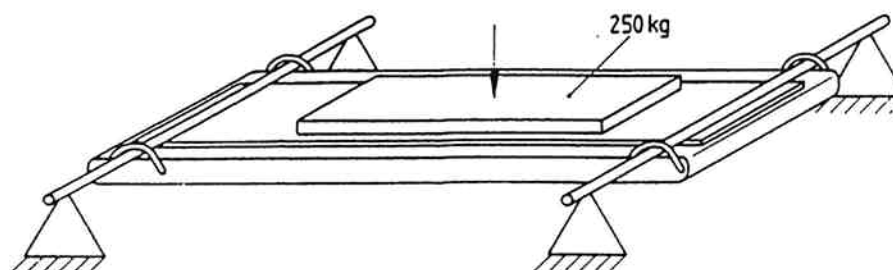


Figure 9

5.7 Long spinal board

5.7.1 Permanent deformation of the frame and lying area

Place the long spinal board on supports positioned 300 mm from the ends of the spinal board. Load spinal board with 250 kg, distributing the weight evenly along the length of the spinal board.

Unload the spinal board and examine for deflections.

5.7.2 Resistance to twisting/torsion

Idem as for the main stretcher (see 5.1.4).

5.8 Foldable carrying chair

5.8.1 Permanent deformation of the frame and backrest lying-sitting area

Place carrying chair handles on supports. Suspend carrying chair by the handles as if the carrying chair was being carried.

Secure the carrying chair handles to the supports with restraint straps to prevent the handles from sliding off the supports.

Load the carrying chair with 250 kg distributing the weight in the carrying chair much as a patient's weight would be distributed.

Following this test, tip the carrying chair back on wheels as if transporting a patient and roll the carrying chair over smooth surfaces, door-sills, minor obstructions, and any other types of surfaces the carrying chair might be rolled across.

Unload the carrying chair and examine for deflections and/or failures. There shall be no remaining deformation or defects.

5.9 Non-foldable carrying chair (sedan chair)

5.9.1 Permanent deformation of the frame and sitting area

Place extended sedan chair handles on supports, suspending carrying chair by the handles as if the carrying chair was being carried.

Secure the carrying chair handles to the supports with restraint straps to prevent the handles from sliding off the supports.

Load the carrying chair with 250 kg, distributing the weight in the carrying chair much as a patient's weight would be distributed.

Unload the non-foldable carrying chair and examine for deflections and/or failures.

5.9.2 Fixation inside the ambulance

Requirements of the fixation shall be in accordance with 4.5.9 of prEN 1789:1999.

5.9.3 Splaying of the wheels

Load the carrying chair with 250 kg. Place the carrying chair on wheels as if transporting a patient and roll the carrying chair over smooth surfaces, door-sills, minor obstructions, and any other types of surfaces the carrying chair might be rolled across.

Unload the carrying chair and examine for deflections and/or failures. There shall be no remaining deformation or defects.

6 Marking

The stretchers and other patient handling equipment covered by this European Standard shall be labelled in accordance with EN 980 and EN 1041.

7 Operating and maintenance instructions

The operating and maintenance instructions for the stretchers and other patient handling equipment covered by this European Standard shall be in accordance with 5.5 of EN 292-2.

NOTE 1: The function of safety equipment has to be described specially and further more advise for the repair of malfunctions should be given.

NOTE 2: The operating and maintenance instructions should be in the native language.

Annex ZA (Informative)

Clauses of this European Standard addressing Essential Requirements or other provisions of Council Directive 93/42/EEC concerning medical devices

This European Standard has been prepared under a mandate given to CEN by the European commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of the standard.

Table ZA.1 lays out which clauses of this standard are likely to support the relevant requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1: Relationship between this standard and Directive 93/42/EEC

| Relevant clause of this standard | Essential requirements from Annex I of Council Directive concerning Medical Devices (93/42/EEC) |
|--|---|
| 4 | 2, 3, 4, 9.2, 12.7 |
| 4.1.8, 4.2.7, 4.3.7, 4.4.7, 4.5.7, 4.6.7, 4.7.7, 4.8.7 | 7.1 |
| 4.1.5, 4.1.6, 4.2.5, 4.3.5, 4.4.5, 4.7.5, 4.8.5, 4.9.5 | 7.3 |
| 5 | 2, 3, 4, 9.2, 12.7 |
| 6 | 13 |

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