BS 8480:2006

BRITISH STANDARD

Medical devices – Chairs with electrically operated support surfaces – Requirements

ICS 97.140

Publishing and copyright information

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Contents

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 4, an inside back cover and a back cover.

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Foreword

Publishing information

This British Standard was published by BSI and came into effect on 31 July 2006. It was prepared by Technical Committee FW/1, *Common test methods for furniture*. A list of organizations represented on this committee can be obtained on request to its secretary.

Information about this document

Manufacturers and importers of chairs with electrically operated support surfaces should be aware that if any part of the marketing of their products can be interpreted as claiming that a product is:

"intended by the manufacturer to be used for human beings for the purpose of:

- treatment or alleviation of disease;
- treatment, alleviation of or compensation for an injury or handicap;"

such chairs are considered to be medical devices and therefore subject to the provisions of EC Directive 93/42 EEC (the Medical Devices Directive) [1].

This British Standard is applicable to chairs that are intended by the manufacturer to be used as medical devices as defined by EC Directive 93/42 (the Medical Devices Directive) [1]. However, the standard is not applicable to chairs that are intended for use during the administration of treatment by a medical practitioner, for example dentists' chairs.

Manufacturers of medical devices are required by law, under the Medical Devices Regulations 2002 [2], to comply with the requirements of the Medical Devices Directive, including being registered with a regulatory body in the EU known as a "competent authority", as being responsible for placing medical devices on the market.

If a company is importing medical devices into the EU and placing them on the market, and the manufacturer, or another importer within the EU, is not registered with a competent authority as being responsible for placing medical devices on the market, that company could acquire all the responsibilities of the manufacturer under the legislation.

All aspects of marketing may be considered when deciding if a product is a medical device, including point of sale claims. Manufacturers who do not have control over claims made at the point of sale are advised to consider whether they should take legal advice regarding their position.

UK manufacturers and importers of medical devices can obtain guidance from the UK competent authority, which at the time of publication of this British Standard is the Medicines and Healthcare products Regulatory Agency (MHRA)[1)].

Useful guidance on the Medical Devices Directive is available from the MHRA web site at www.mhra.gov.uk which includes guidance notes for manufacturers of Class 1 medical devices and guidance notes for the registration of persons responsible for placing devices on the market.

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1) Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Tel: 020 7084 2000.

Hazard warnings

WARNING. This British Standard calls for the use of procedures that can be injurious to health if adequate precautions are not taken. It refers only to technical suitability and does not absolve the user from legal obligations relating to health and safety at any stage.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are presented in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

1 Scope

This British Standard specifies safety requirements for chairs with support surfaces the position of which can be adjusted electrically by the seated person and/or an attendant, including reclining chairs and riser chairs. It is applicable to chairs for use by a person weighing up to 100 kg. The standard is not applicable to multiple seating units.

In the text of this standard the term "chairs" is used to refer to chairs with electrically operated support surfaces.

This British Standard is applicable to chairs that are intended by the manufacturer to be used as medical devices as defined by EC Directive 93/42 (the Medical Devices Directive) [1].

The standard is not applicable to chairs that are intended for use during the administration of treatment by a medical practitioner, for example dentists' chairs.

NOTE Chairs with electrically operated support surfaces that are not intended by the manufacturer to be used as medical devices are specified in BS 8474.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS 8474:2006, *Furniture – Chairs with electrically operated support surfaces – Requirements*

BS EN 14971:2001, *Medical devices – Application of risk management to medical devices*

BS EN 12182:1999, *Technical aids for disabled persons – General requirements and test methods*

3 Terms and definitions

For the purposes of this British Standard the terms and definitions given in BS 8474:2006 and the following apply.

3.1 manufacturer

natural or legal person with responsibility for the design, manufacture, packaging and labelling of a chair before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party [European Council Directive 93/42 of 14 June 1993 (the Medical Devices Directive) Article 1.2 (f) Paragraph one [1]]

4 Requirements

4.1 Risk management

A risk analysis shall be carried out in accordance with BS EN 14971 and shall include the hazards and risks given in BS EN 12182:1999, **5.1**, **5.2**, **5.4.2**, **5.5**, Clause **6**, **8.2.1**, **9.4**, Clause **10**, Clause **21** and Clause **24**.

NOTE 1 The risk analysis should include consideration of hazards associated with the following:

a) the user, who might have one or more disabilities;

b) carers, who might be elderly and/or have disabilities;

c) healthcare personnel, who might not have been trained in the use of the chair and who might need to operate the chair adjustments whilst treating or caring for the user;

d) children, particularly young children, who might play around the chair out of the sight of the user and/or carer;

e) pets, particularly those that might access the inner mechanism of the chair;

f) other persons living in or visiting the user's environment, who might not have been trained in the use of the chair.

NOTE 2 If, at the conclusion of the overall residual risk evaluation (as specified in BS EN 14971:2001, Clause 7), the manufacturer concludes that the intended benefits outweigh the residual risk, he has an obligation to ensure that appropriate warnings and safety instructions are clearly, permanently and prominently applied to the chair and associated literature.

4.2 General requirements

4.2.1 Chairs shall conform to the requirements specified in BS EN 12182:1999 for the parameters listed in Table 1.

Table 1 **Requirements specified in BS EN 12182**

Parameter	**Requirement specified in BS EN 12182:1999 clause**
Intended performance and technical documentation	**4.2**
Clinical evaluation	**4.3**
Aids that can be dismantled	**4.4**
Single use fasteners	**4.5**
Flammability	**5.1**
Biocompatibility and toxicity	**5.2**
Contaminants and residues	**5.3**
Infection and microbiological contamination	**5.4**
Electromagnetic compatibility	Clause **7**
Electrical safety	**8.1**
Overflow, spillage, leakage and ingress of liquids	Clause **9**
Information supplied by the manufacturer	Clause **23**

4.2.2 In addition, chairs shall conform to the requirements specified in BS 8474:2006, with the exception of the requirement for information to be supplied by the manufacturer, as specified in BS 8474:2006, Clause **9**.

4.3 Back-up power supply

Chairs shall be fitted with an internal power source capable of operating all the electrically powered support surfaces through the full range of movement, including return to the starting position, not less than six times, in the event of failure of the electrical supply mains.

Bibliography

[1] EUROPEAN COMMUNITIES. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Luxembourg: Office for Official Publications of the European Communities, 1993.

[2] GREAT BRITAIN. The Medical Devices Regulations 2002, SI 2002 No. 618 (as amended). London: The Stationery Office.

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