

Quality systems — Medical devices — Particular requirements for the application of EN ISO 9002 (revision of EN 46002:1996) (identical to ISO 13488:1996)

The European Standard EN ISO 13488:2000 has the status of a British Standard

ICS 03.120.10; 11.040.01

National foreword

This British Standard is the official English language version of EN ISO 13488:2000. It is identical with ISO 13488:1996. It supersedes BS EN 46002:1997 which will be withdrawn on 15 February 2004.

The UK participation in its preparation was entrusted to Technical Committee CH/66, Quality systems for the manufacture of medical devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/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.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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Summary of pages

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