

Enteral feeding catheters and enteral giving sets for single use and their connectors — Design and testing

The European Standard EN 1615:2000 has the status of a
British Standard

ICS 11.040.20

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

National foreword

This British Standard is the official English language version of EN 1615:2000. It supersedes BS EN 1615:1997 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/27, Medical plastics tubing, 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.

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

Cross-references

The British Standards which implement international or European publications referred to in this document 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.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 14, an inside back cover and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 December 2000

© BSI 12-000

ISBN 0 580 36668 5

Amendments issued since publication

Amd. No.	Date	Comments

English version

Enteral feeding catheters and enteral giving sets for single use and their connectors - Design and testing

Sondes et dispositifs de nutrition entérale non réutilisables
et leurs raccords - Conception et essais

Katheter und Überleitungsgeräte zur enteralen Ernährung
und ihre Konnektoren zur einmaligen Verwendung -
Ausführung und Prüfung

This European Standard was approved by CEN on 16 September 2000.

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
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents

	Page
Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	6
4 Requirements	6
Bibliography	14

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205, Non-active medical devices, the Secretariat of which is held by BSI.

This European Standard replaces EN 1615:1997.

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 April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

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 specifies requirements for single-use enteral feeding catheters and enteral giving sets and their connector systems.

The requirements for enteral feeding catheters, giving sets and their connections are specified so that, when used in current clinical practice, these devices do not compromise the clinical condition or the safety of patients.

Some general requirements are covered by reference to other European Standards listed in the normative references clause. This European Standard contains informative references to other European Standards listed in the Bibliography.

Enteral feeding catheters are intended for human enteral nutrition. They are designed to pass the nutrition solutions through the nose or mouth, or by gastrostomy, jejunostomy or oesophagostomy.

Both enteral giving sets and enteral feeding catheters are often used with enteral nutrition pumps. The performance and connecting system requirements are specified so that both devices and their connections perform safely.

It is important that enteral giving sets should not be able to be connected to parenteral intravascular catheters or any other catheter with a female Luer connector. The requirements for the connecting systems prevent this form of misconnection.

There are many enteral giving sets and enteral feeding catheters on the market which perform satisfactorily. This standard specifies three connectors suitable for enteral giving sets. It has not been found possible or desirable to limit the standard to only one connector. This places the onus on the designers and manufacturers of the enteral feeding catheters to provide connectors on their devices which mate with the connector on the enteral giving set and conform to the appropriate clauses of this standard. The report from the Task Force Group, Luer Fittings, under the auspices of the CEN Health Care Forum has been noted. A revision of the present standard will be undertaken when an appropriate solution has been decided for alternative connector systems for enteral use.

It was not considered necessary to provide a colour code on the enteral giving set, because the connectors specified for the enteral giving set will not fit into a female Luer fitting. Also, many enteral feeding catheters use a colour code on the connector to indicate the diameter of the catheter, and this could cause confusion with any colour suggested for coding the enteral giving set.