Irish Standard
I.S. EN 15546-1:2008

Small bore connectors for liquids and gases in healthcare applications - Part 1 - General Requirements

I.S. EN 15546-1:2008

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:* EN 15546-1:2008	*Published:* 21 May, 2008

This document was published under the authority of the NSAI and comes into effect on:
18 November, 2008

ICS number:
11.040.10

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Price Code:
I

Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN 15546-1:2008

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15546-1

May 2008

ICS 11.040.10

English version

Small bore connectors for liquids and gases in healthcare applications - Part 1 - General Requirements

Raccords de petite taille pour liquides et gaz dans les applications médicales - Partie 1 : Exigences générales

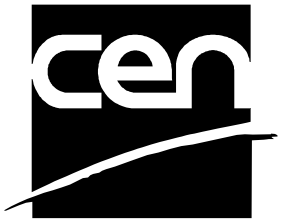
Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen

This European Standard was approved by CEN on 21 March 2008.

CEN and CENELEC 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 CEN Management Centre or to any CEN or CENELEC 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 and/or CENELEC member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



CEN Management Centre:
rue de Stassart, 36 B-1050 Brussels

CENELEC Central Secretariat:
rue de Stassart, 35 B-1050 Brussels

Ref. No. EN 15546-1:2008 E

Contents

Page

Foreword

This document (EN 15546-1:2008) has been prepared by CEN/BT/TF 123 "'Small-bore connectors for liquids and gases in healthcare applications", the secretariat of which is held by AFNOR.

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 November 2008, and conflicting national standards shall be withdrawn at the latest by November 2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

Following the recommendations given in the CEN Report 13825, Luer connectors - A report to CEN CHeF from the CEN forum task group "Luer fittings", this European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This part 1 of the standard contains general requirements to ensure the prevention of cross-connection between small bore connectors used in different fields of medical applications. It is intended that subsequent parts include the dimensions and drawings of connectors allocated to specific medical applications.

This European Standard supports the essential requirements of the 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

In the 1990s concern grew regarding the proliferation of devices fitted with Luer connectors and the reports of patient death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases.

Concerns regarding the use of Luer connectors with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997 the newly-created CEN Healthcare Forum (CheF) steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report “CR 13825:2000" [2], in which they concluded that there is a problem arising from the application of a single connector design to a number of incompatible applications. In a coronary care unit there are as many as 40 connectors on the devices used with a single patient. Therefore, it is not surprising that misconnections are made.

For many years medical devices have followed the established principle of “safety under single fault conditions”. Simply stated, this means that a single fault should not result in a hazard. This principle is embodied in the requirements of numerous medical device standards. Extending this principle to the application of Luer connectors, i.e. that misconnection should not result in a patient hazard, the FTG recommended that the Luer connector should be restricted to devices intended to be connected to the vascular system or a hypodermic syringe. In addition, new designs of small bore connector should be developed for non-intravascular applications, and these should be incompatible with Luer connectors and each other.

NOTE Condition in which a single means for reducing a RISK is defective or a single abnormal condition is present.

The Medical Device Directive 93/42/EEC addresses this type of problem in Essential Requirement 1.2. (*solutions adopted for the design and construction of devices must conform to safety principles, taking into account the generally acknowledged state of the art. In seeking the most appropriate solutions, the manufacturer must apply the following principles in the following order:*

> *eliminate or reduce risk as far as possible (inherently safe design and construction, etc.*)
>
> and 9.1 *(if the device is intended for use in combination with other devices or equipment, the whole combination, including the connector system must be safe, etc.*)

CEN/BT/Task Force 123 ‘Small bore connectors for liquids and gases in healthcare applications’ was established to carry forward the recommendations of CR 13825 [2]. It was recognised that small bore connector systems could not be designed to overcome all chances of misconnection or to eliminate deliberate misuse. However, a number of steps could be taken that would improve the current situation and lead to greater patient safety. This will only be achieved through a long-term commitment involving industry, healthcare professionals, device purchasers and medical device regulatory authorities.

This part 1 of European Standard and its parts are intended to be the reference documents in which all designs of small bore connectors for medical applications are listed. CEN/BT/TF 123 has developed this series of Standards in such a way that the standard includes general requirements to ensure the prevention of cross-connection between connectors used in different fields of medical application.