Anesteetilised ja hingamisseadmed. Mittevahetatavad kruvikeermega (NIST) madalsurve ühendusliitmikud meditsiinilistele gaasidele

Anaesthetic and respiratory equipment - Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 15908:2010 sisaldab Euroopa standardi EN 15908:2010 ingliskeelset teksti.	This Estonian standard EVS-EN 15908:2010 consists of the English text of the European standard EN 15908:2010.
Standard on kinnitatud Eesti Standardikeskuse 30.11.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 06.10.2010.	Date of Availability of the European standard text 06.10.2010.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15908

October 2010

ICS 11.040.10

English Version

Anaesthetic and respiratory equipment - Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases

Matériel respiratoire et anesthésique - Raccords basse pression à tête filetée non interchangeables (NIST) pour gaz médicaux

Anästhesie- und Beatmungsgeräte - Nichtverwechselbare Verbindungsstücke mit Schraubgewinde (NIST) für niedrigen Druck zur Verwendung mit medizinischen Gasen

This European Standard was approved by CEN on 28 August 2010.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 15908:2010: E

Contents

Page

Foreword

This document (EN 15908:2010) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

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 2011, and conflicting national standards shall be withdrawn at the latest by April 2011.

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.

This document 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 document.

Requirements for non-interchangeable screw-threaded (NIST) connectors are currently specified in EN ISO 5359:2008. The requirements for NIST connectors in EN 15908 are identical to those currently given in EN ISO 5359:2008 except for:

— the allocation of connector B11 (allocated to carbon dioxide instead to carbon dioxide/oxygen mixture [CO_2 > 7 % (volume fraction)]);

— the allocation of connector C 19 (allocated to carbon dioxide/oxygen mixture [CO_2 > 7 % (volume fraction)] instead to carbon dioxide).

It is intended that EN ISO 5359:2008 will be revised so as to delete the requirements for NIST connectors.

The requirements for NIST connectors in EN 15908 are identical to those given in EN 739:1998 (cancelled and replaced by EN ISO 5359:2008) except for:

— the allocations of connectors B11 (allocated to carbon dioxide only);

— the allocation of connector C19 (allocated to carbon dioxide/oxygen mixture [CO_2 > 7 % (volume fraction)] only);

— the allocation of connector B12 to oxygen-enriched air;

— the allocation of connector B15 to helium/oxygen mixture [O_2 < 20 % (volume fraction)] only;

— the allocation of connector C20 to helium only.

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, Croatia, 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

This European Standard has been prepared in response to the need for a safe method of connecting medical equipment intended to administer medical gases to patients. Medical gases are stored in cylinders or cryogenic vessels, or can be produced on site; several medical devices, e.g. pressure regulators, hose assemblies, flow-metering devices, lung ventilators, anaesthetic workstations can be fitted between the source of supply and the patient. At each interface gas-specific connectors are needed to ensure that the intended medical gas is administered to the patient.

While recognizing that no system is absolutely safe, this European Standard includes those requirements considered necessary to prevent foreseeable hazards arising from the use of connectors. Operators should be continually alert to the possibility of damage being caused by external factors, and therefore regular inspection should be undertaken to ensure that connectors continue to meet the requirements of this European Standard.

The choice of a single system of connectors to be used within the European Union will minimize the risks of cross connections and misconnections and ensure the free movement of medical devices intended to administer medical gases to patients.

1 Scope

1.1 This European Standard specifies requirements for connectors intended for use with medical gases.

1.2 This European Standard specifies the dimensions and the allocation of non-interchangeable screw-threaded (NIST) connectors intended to be used at nominal operating pressures not greater than 1 400 kPa.

NOTE As stated in EN ISO 5359, gas-specific quick-connectors conforming to EN ISO 9170-1 are considered as an alternative to NIST connectors.

1.3 The information to be supplied by the manufacturer is excluded from the scope of this European Standard because information about the use of NIST connectors is supplied by the manufacturer of each medical device to which the connectors are permanently fitted.

2 Normative references

The following referenced document is 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.

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
gas-specific
having characteristics which prevent interchangeability, thereby allowing assignment to only one gas service or vacuum service

3.2
medical gas
gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

NOTE For the purposes of this European Standard, this term includes vacuum, air and nitrogen for driving surgical tools.

3.3
NIST connector
non-interchangeable screw-threaded connector
any of a range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters and a left-or right-hand screw thread to the mating components for each particular gas

4 General requirements

4.1 Safety

NIST connectors shall, when permanently fitted onto a medical device and operated in normal use and maintained according to the instructions of the manufacturer of the medical device, present no risks that are