



SLOVENSKI STANDARD
SIST EN 15154-4:2009
01-junij-2009

Varnostne prhe za prvo pomoč - 4. del: Prenosni pripomočki za spiranje oči

Emergency safety showers - Part 4: Non plumbed-in eyewash units

Sicherheitsnotduschen - Teil 4: Augenduschen ohne Wasseranschluss

Douches de sécurité - Partie 4: Unités de lavage d'yeux non raccordées au réseau d'eau

Ta slovenski standard je istoveten z: EN 15154-4:2009

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 15154-4

March 2009

ICS 71.040.10

English Version

Emergency safety showers - Part 4: Non plumbed-in eyewash units

Douches de sécurité - Partie 4: Unités de lavage d'yeux
non raccordées au réseau d'eau

Sicherheitsnotduschen - Teil 4: Augenduschen ohne
Wasseranschluss

This European Standard was approved by CEN on 21 February 2009.

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, 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.

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Foreword

This document (EN 15154-4:2009) has been prepared by Technical Committee CEN/TC 332 "Laboratory equipment", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by September 2009.

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.

EN 15154 consists of the following parts, under the general title *Emergency safety showers*

- Part 1: Plumbed-in body showers for laboratories
- Part 2: Plumbed-in eye wash units
- Part 3: Non plumbed-in body showers
- Part 4: Non plumbed-in eyewash units
- Part 5: Plumbed-in body showers for production facilities (in planning)

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

The first seconds after an accident in which the eyes have been exposed to harmful substances are critical to keep the eye injury to a minimum. Non plumbed-in emergency safety eyewash units are designed and intended to be kept in the immediate proximity of persons working in a potentially hazardous area. The main purpose of these devices is to supply immediate primary flushing.

Non plumbed-in emergency safety eyewash units can also allow continued flushing on the way to medical care.

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1 Scope

This European Standard is a product specification, giving minimum performance requirements for non plumbed-in emergency safety eyewash units.

It is applicable to non plumbed-in emergency safety eyewash units filled with a rinsing fluid by the manufacturer for first aid use when the eyes have been exposed to harmful substances.

Requirements are also given concerning labelling, marking and information to be supplied by the manufacturer.

Throughout this standard, the term "non plumbed-in emergency safety eyewash unit" is referred to as "eyewash unit".

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.

EN 556-1, *Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices*

EN 556-2, *Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 2: Requirements for aseptically processed medical devices*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

3 Terms and definitions

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

3.1

non plumbed-in eyewash unit

self contained device specially designed and intended to deliver a flushing fluid to irrigate and flush the eye(s) when exposed to harmful substances

3.2

transportable eyewash unit

non plumbed-in eyewash unit that is a movable device

3.3

portable eyewash unit

non plumbed-in eyewash unit that is designed to be carried by a single person unaided and kept or mounted in immediate proximity of the user to supply immediate flushing

3.4

personal eyewash unit

non plumbed-in eyewash unit that is designed to be carried by and on the user, in a pocket or a holster

3.5

single use eyewash unit

non plumbed-in eyewash unit designed to deliver a single application of rinsing fluid

EN 15154-4:2009 (E)**3.6****multiple use disposable eyewash unit**

non plumbed-in eyewash unit designed to deliver multiple applications of rinsing fluid prior to disposal

EXAMPLE Pressurised spray-cans.

3.7**reconditionable eyewash unit**

non plumbed-in eyewash unit designed to be reconditioned

3.8**effective volume**

minimum volume of fluid that can be dispensed from the unit during intended operation

4 Performance requirements**4.1 Efficacy**

The efficacy of the product shall be sufficient to reduce the effects of harmful substances.

4.2 Quality of rinsing fluid**4.2.1 General**

The rinsing fluid shall be non toxic and safe for the user during the entire shelf life of the product.

The rinsing fluid shall be water or solutions.

4.2.2 Water

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If water is used in eyewash units, it shall be potable water or water of a similar quality, wherein germ multiplication is prevented.

NOTE Potable water is defined in the European Directive 98/83/EC.

4.2.3 Solutions

If saline solutions, buffered solutions or other solutions are used in eyewash units, the solutions shall be sterile according to EN 556-1 or EN 556-2.

NOTE Attention is drawn to European Directives MDD 93/42/EEC and Medicine products 2001/83/EC.

4.3 Flow

The flow pattern shall ensure rinsing of the entire area of the eye(s) including the eyelids.

The design of eyewash units shall ensure that the pressure of the fluid at the point of delivery is minimised so as not to cause injury to the eye.

The design of the device shall allow for continuous flow of the rinsing fluid.

4.4 Container for rinsing fluid

4.4.1 General

Eyewash units shall be designed in such a way as to be non hazardous to the user.

Materials used in the construction of eyewash units shall not affect the quality of the fluid nor shall the fluid affect the materials of the container during the shelf life of the product.

NOTE 1 The European Directive PED 97/23/EC can apply for certain pressurised units.

NOTE 2 The number of eyewash units positioned in any work place location can be determined by the risk assessment for that location.

4.4.2 Transportable eyewash units

Transportable eyewash units with a mass between 2 kg and 15 kg shall have handles or shall be able to be moved with a transport tool intended for this.

With a mass greater than 15 kg, they shall be fitted with wheels if they are intended to be moved by a single person.

4.4.3 Portable eyewash units

Portable eyewash units shall have a mass less than 2 kg. They shall be designed to allow the user to firmly grip the unit with one hand.

The minimum effective volume shall be 400 ml for water. Portable eyewash units containing other solutions shall have an effective volume to achieve at least equivalent efficacy.

4.4.4 Personal eyewash units

The effective volume of personal eyewash units shall be sufficient to provide immediate flushing while further fluid is obtained.

The minimum effective volume shall be 150 ml for water. Personal eyewash units containing other solutions shall have an effective volume to achieve at least equivalent efficacy.

The design of the personal eyewash unit shall allow it to be carried in a pocket or a holster without hindering movement during work.

5 Functional Requirements

5.1 General

Eyewash units shall be able to be activated for immediate use by a single person within a maximum of 5 s, even with closed eyes. Once activated, it shall be possible to operate the device with one hand.

5.2 Single use eyewash units

Single use eyewash units shall be fitted with a tamper-evident device.

5.3 Multiple use eyewash units

The device shall be designed so that it can be checked that it is fit and ready for use.