

SLOVENSKI STANDARD SIST EN 15154-3:2009

01-junij-2009

Varnostne prhe za prvo pomoč - 3. del: Prenosne prhe za spiranje telesa

Emergency safety showers - Part 3: Non plumbed-in body showers

Sicherheitsnotduschen - Teil 3: Körperduschen ohne Wasseranschluss

Douches de sécurité - Partie 3: Douches pour le corps non raccordées au réseau d'eau

(standards.iteh.ai) Ta slovenski standard je istoveten z: EN 15154-3:2009

SIST EN 15154-3:2009

https://standards.iteh.ai/catalog/standards/sist/ae59ea1b-0a06-4ada-b110-97f39979a04d/sist-en-15154-3-2009

ICS:

11.160 Prva pomoč71.040.10 Kemijski laboratoriji. Laboratorijska oprema First aid Chemical laboratories. Laboratory equipment

SIST EN 15154-3:2009

en,fr,de



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SIST EN 15154-3:2009

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 15154-3

March 2009

ICS 71.040.10

English Version

Emergency safety showers - Part 3: Non plumbed-in body showers

Douches de sécurité - Partie 3: Douches pour le corps non raccordées au réseau d'eau

Sicherheitsnotduschen - Teil 3: Körperduschen 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.

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Ref. No. EN 15154-3:2009: E

SIST EN 15154-3:2009

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Foreword

This document (EN 15154-3:2009) 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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by September 2009.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 DARD PREVIEW
- 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 body or parts of the body have been exposed to harmful substances or heat are critical to keep the injury to a minimum. Non plumbed-in emergency safety body showers 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 first aid.

Non plumbed-in emergency safety body showers can also allow continued washing 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 body showers.

It is applicable to body showers filled with a washing fluid by the manufacturer and to empty devices to be filled prior to putting into service. Both variations are for first aid use when the body or parts of the body have been exposed to harmful substances or heat.

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 body shower" is referred to as "body shower".

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 **REVIEW**

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

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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 body shower

self contained device specially designed to reduce the amount of harmful substances or heat by a cascading or spraying of washing fluid on the body or parts of the body

3.2

fixed body shower

non plumbed-in body shower which is designed to be in a fixed and stationary position

3.3

transportable body shower

non plumbed-in body shower that is a movable device

3.4

portable body shower

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

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3.5

single use body shower

non plumbed-in body shower designed to deliver a single application of washing fluid

3.6

multiple use body shower

non plumbed-in body shower designed to deliver multiple applications of washing fluid

3.7

refillable body shower

non plumbed-in body shower designed to be refilled after use

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 and/or heat.

4.2 Quality of washing fluid iTeh STANDARD PREVIEW

4.2.1 General

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

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The washing fluid shall be water or solutions, ai/catalog/standards/sist/ae59ea1b-0a06-4ada-b110-97f39979a04d/sist-en-15154-3-2009

4.2.2 Water

If water is used in body showers, it shall be potable water or water of a similar quality.

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 body showers, the solutions shall be sterile according to EN 556-1 or EN 556-2.

NOTE Attention is drawn to European Directive MDD 93/42/EEC.

4.3 Flow

Body showers shall be designed to provide a controlled flow of washing fluid to any portion of the body at a velocity low enough to be non injurious.

The flow pattern and the volume shall ensure proper washing/heat reduction according to the manufacturer's specified field of application.

4.4 Container for washing fluid

4.4.1 General

Body showers shall be designed in such a way as to be non hazardous to the user.

Materials used in the construction of body showers 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.

The effective volume of body showers shall be sufficient to provide immediate washing while further fluid is obtained, if necessary.

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

4.4.2 Fixed body showers

The minimum effective volume shall be 100 I for water. Fixed body showers containing other solutions shall have an effective volume to achieve at least equivalent efficacy, which shall be proven by the manufacturer.

4.4.3 Transportable body showers

4.4.4 Portable body showers

Transportable body showers shall be fitted with wheels/rollers/others in order to be easily handled and moved.

If water is used, the minimum effective volume shall be 15 I. Transportable body showers containing other solutions shall have an effective volume to achieve at least equivalent efficacy, which shall be proven by the manufacturer.

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Portable body showers shall have a mass of less than 15 kg. They shall be designed to allow the user to firmly grip the unit. 97f39979a04d/sist-en-15154-3-2009

If water is used, the minimum effective volume shall be 10 l. Portable body showers containing other solutions shall have an effective volume to achieve at least equivalent efficacy, which shall be proven by the manufacturer.

Portable body showers specifically designed for heat reduction of thermal burns may have an effective volume of less than 10 I and shall be marked accordingly (see 6.1 j).

5 Functional Requirements

5.1 General

Body showers shall be able to be activated for immediate use by a single person within a maximum of 5 s.

If the unit is intended to be handheld, the shower shall allow the user to distribute the washing fluid with one hand.

Once the shower has been activated, it shall be possible to temporarily deactivate it, to save washing fluid.

5.2 Single use body showers

Single use body showers shall be fitted with a tamper-evident device.