

Safety showers



Synthesis of the
European Standard

EN 15154

CEN
TC 332

Published and takes effect since June 2009



PREVOR

ANTICIPATE AND SAVE

Toxicology Laboratory & Chemical Risk Management

Foreword:



This project for the development of a European Standard deals with safety showers and started in 2002-2003; it is based on what is commonly accepted as being, in the 27 countries of the European Union, the most common technical standards and in theory, the most advanced ones.

It has given a legislative and qualitative framework for all safety shower facilities.

OVERVIEW OF

THE STANDARD



- **European Standard Project**
 - Technical Committee CEN/TC 332 « Laboratory Equipment»
 - Secretaryship operated by the DIN (Deutsches Institut für Normung)
 - Standard project → prEN 15154
 - **National mirror committees aiming at evaluating national standards as well as « acceptable » planning for their country**
 - Spiegelgremium of the DIN in Germany
 - UNM 61 for France.
 - **Centralized synthesis, operated with national delegations at a European committee level, including representatives of each country**
 - **Launching of the project in 2003 – Agreement on final versions – 2008**
 - **3 official writing languages : French, German, English**
- > **The normative principles consist of:**
- Relying on existing standards
 - Realizing their synthesis
- **Obtaining a key compromise at the European level: European objective / national requirements**



OBJECTIVE

Achieving a European (technical) standard and avoiding potential conflicts amongst national standards.

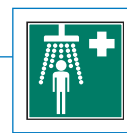
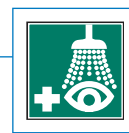
Prevor's objective:

Integrating a recognition for devices not plumbed to water supply in order to give an alternative to the classical "water shower" and to be part of the recognised technical and technological standards - Ensuring that companies using our solutions are not left out of the standard.

It comes in 4 parts so far:

- Plumbed-in body showers for laboratories 15154-1
- Plumbed-in eye wash units- 15154-2
- 15154-3 and 15154-4 parts deal more specifically with non-plumbed safety shower for the body (part 3) and the eye (part 4)
- Regarding parts 3 and 4, they rely on the reference texts concerning medical devices (European Directive on medical devices (93/42/EEC) and EN 556-1 and 556-2 standards linked to the medical devices sterilization)





PART 1



PLUMBED-IN BODY SHOWERS

Principle > either mechanically wash or sufficiently dilute the substances to render them harmless

- **Flow rate: in accordance with the national legislations**
 - If no legislation = 60 l./min. is suitable
 - 15 minutes of performance– 95% of flow rate in diameter of 40 cm in order to avoid all risks of flooding...
 - Non dangerous flow rate for the user
- **Water quality**
 - Potable water or water with a similar quality
 - No « contamination » due to the materials used in the construction of the system
- **Temperature**
 - Hypothermia risk; minimum recommended water temperature of 15°C (in annex)
- **Information to be provided by the manufacturer:**
 - Installation, operating and maintenance
 - Method and frequency of routine testing
 - Marking to identify the manufacturer (on the shower)

PART 2



PLUMBED-IN EYE WASH UNITS

Principle > either mechanically wash or sufficiently dilute the substances to render them harmless

- **Flow rate**
 - 6 l./min. 1000mm (+/-200) for installation
 - 15 minutes of continuous performance
 - Non dangerous flow rate for the user (jet height between 100 and 300mm)
 - Valve operational in 1 s.



- **Water quality**
 - Potable water or water with a similar quality
 - No « contamination » due to the materials used in the construction of the system
- **Temperature**
 - Hypothermia risk; recommended T° of 15°C (in annex)
- **Information to be provided by the manufacturer:**
 - Installation, operating and maintenance
 - Method and frequency of routine testing
 - On the shower: marking to identify the manufacturer

- **Areas of application:**

System enabling either a decontamination at the place of the accident or a decontamination during the transport to the hospital.

PART

3

**NON- PLUMBED-IN BODY SHOWERS***Performance requirements*

> either mechanically wash or sufficiently dilute the substances to render them harmless

- **Solution quality:**

- Innocuousness during the entire life time
- Water or Solutions (if water, potable water quality or similar)
- Solutions – Have to be sterile
- Non dangerous flow rate

- **Packaging**

- Packaging specifications:**

- Dependant on the type of packaging and the solution/weight and volume
- Operational within 5s.



PART

4

**NON- PLUMBED-IN EYE WASH UNITS***Performance requirements*

> Sufficient volume and protocol > for harmless decontamination agent (or temperature)

- **Solution quality**

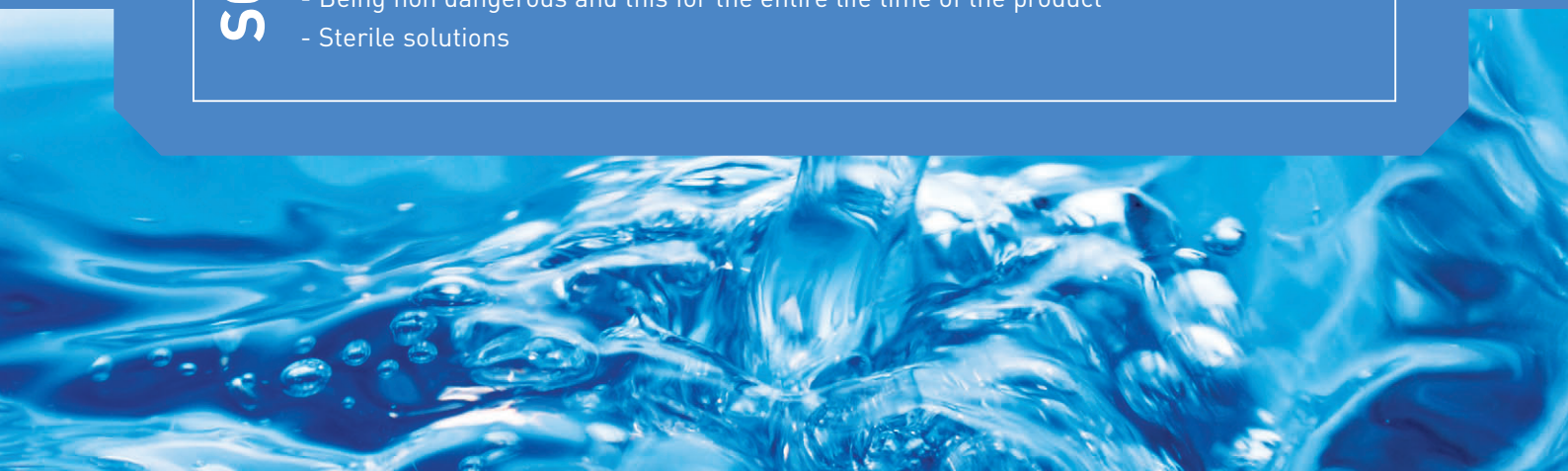
- Innocuous during the entire life time
- Water or solutions (if water, potable water quality or similar)
- Solutions – Have to be sterile

- **Packaging specifications**


- Depend on the type packaging and the solution/weight and volume
- Operational within 5s.

**OBJECTIVES AND SPECIFICATIONS****SOLUTIONS**

- Reduce the aggressiveness of the dangerous product
- For water- based solutions, a minimum capacity is established for the skin (10l) as well as for the eye (150ml) ; any exemptions must be justified by effectiveness
- Effectiveness must be significantly proved in comparison with the water and the different amounts of alternative solution and, as such, it is left up to the manufacturer to prove its effectiveness. (Refer to the list of tested products and used method)
- What evidences of effectiveness?
- Being non dangerous and this for the entire life time of the product
- Sterile solutions



INFORMATION OF COMPLIANCE PREVOR AND OTHER DEVICES

	Standard compliance specification requirements	Standard compliance	Non-conformance to the standard
PEVOR'S SOLUTIONS 	<ul style="list-style-type: none"> • Innocuousness of the solution • Areas of effectiveness • Contra-indications and limits of efficacy • Protocol for claimed results • Installation recommendations • Protocol 	Sterility and Innocuousness of the solution Medical device class IIa Effectiveness proved on family of products Available list Contra-indications and limits of efficacy mentioned and available Available protocol and instructions of use Available installation recommendations Duration of use and intervention time communicated in a common and reliable protocol Commitment from the manufacturer on the clear efficacy with defined specifications of use	
SODIUM CHLORIDE SOLUTIONS	<ul style="list-style-type: none"> • Innocuousness of the solution • Defined protocol for efficacy • List of contra-indications 	Sterile and isotonic solution	Claimed rinsing solution for dusts or foreign bodies To specify: do not use on chemical products because of the dilution effect

ANNEXES & REFERENCES

Used reference for the standard EN 15154:

- Norme EN 420 on protective gloves
- Norme ISO 3864 : graphic symbols : safety colours and features– Part 1
- Norme EN 556-1, -2: medical devices sterilization
- Norme EN 980: graphic symbols for medical devices use
- Norme EN 1041: information on medical devices transferred by the manufacturer

→ **DIN** - Deutsches Institut für Normung

- 12899-3 : safety showers in the industry
- Sicherheitsnotduschen Im Labor – Standard on safety showers

→ **ANSI** – American National Standard Institute

- Z 358.1-1998



• Concepts and terms:

- Safety showers – Emergency Safety Shower
- Plumbed-in body showers
- Non plumbed-in body showers
- Safety eyewash unit
- Plumbed-in eye wash units
- Non- plumbed-in eye wash units



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KEY INFORMATION TO BE PROVIDED BY THE MANUFACTURER:

The manufacturer shall provide the user with the following information:

- **ON THE LABEL** or separately (according to EN 1041 and EN980)
 - Name and address of the manufacturer (Prevor, F-95 Valmondois)
 - Details for the product identification (: LPM Diphoterine) -
 - Mention of sterility and sterilization method
 - Batch code
 - Expiration date as YEAR / Month / Day
 - Single use
 - Storage and handling conditions
 - Special operating instructions: how to turn on in case of problems...
 - Contra-indications: Do not use on a particular product category
 - Purpose of Product: scope, etc.
 - Volume

In the form of instructions of use, user guide, instruction, if not possible on the label

- Chemical products or substances that the product can decontaminate
- How to use the product (poster of use)
- Contra-indications
- Recommendations for installation and use + maintenance
- Rechargeable means if rechargeable system



CONCLUSION

Our Prevor washing solutions for chemical splashes are in compliance with the European standard EN 15 154 and provide the user with a clear protocol of use for a claimed result of efficiency.

Our solutions are innocuous and have been positively tested on a list of products and their potential limits are known.

The information of compliance with the standard are not generally mentioned by the solutions available on the market (phosphate or borate buffers, sodium chloride solutions) because they are generally not compatible in terms of safety or efficiency with the criteria of EN 15154 standard.