

EU **DECLARATION** of Conformity (DOC)

Our mission is as it has always been :

Eliminating LTIs (i.e., lost-time injuries) for seaborne workforces.

Scandia Gear is heavily invested in ensuring that our products' CE certifications are both comprehensive and up-to-date.

To us, product and regulatory details are critical to workplace safety.

The new EU PPE Regulation 2016/425 requires that manufacturers make available to wearers and users a DOC for every item of CE-certified PPE (personal protective equipment) produced.

A DOC is a legally-binding document that confirms that a product meets the requirements of applicable safety directives.

Scandia's DOC contains the following information :

- Name/address of manufacturer
- Model and/or serial number of equipment
- List of relevant directives
- List of applicable standards (including amendments and effective dates)
- Declaration statement
- Certificate number
- Name, address, and number of the Notified body responsible for certification
- Name and position of signee
- Signature
- Date

Please see the following page for this product's DOC.

If you have any questions, please contact Scandia's Sales Department.

CE DECLARATION OF CONFORMITY

Plum Eyewash 0.9% Sodium Chloride

Eye irrigation fluid for first aid

We, the manufacturer, of the products covered by this declaration, hereby declare, that the bottles with sterile irrigation fluid listed below, meet the requirements in the Council Directive 93/42/EEC of 14 June 1993, the Directive 2007/47 /EC and its relevant transposition into national laws of the member states into which we place the device. Plum Safety ApS is responsible for the Declaration of Conformity concerning the medical devices listed below:

Art No	Art Name	Volume
5160	Plum Eyewash 0.9% Sodium Chloride QuickRinse	20ml
4691	Plum Eyewash 0.9% Sodium Chloride	200ml
4604	Plum Eyewash 0.9% Sodium Chloride	500ml
4707	Plum Eyewash 0.9% Sodium Chloride	1000 ml
4861	Plum Eyewash 0.9% Sodium Chloride DUO	500ml
4800	Plum Eyewash 0.9% Sodium Chloride DUO	1000 ml

With the intended purpose:

Plum Eyewash 0.9% Sodium Chloride is to be used as a first aid product for eye irrigation.

We guarantee and declare that:

1. The device is a Class Is device according to Annex IX, rule 5.
2. The irrigation fluid is STERILE
3. The planning and manufacture procedures are conducted in conformity with the Company Quality System, in compliance with the provisions of Annex VII combined with Annex V to the Directive.

The notified body DNV Product Assurance AS (ID No.2460) certifies Plum Safety ApS.

The latest EC Certificate No. 10000457813-PA-NA-DNK 2021-05-05.

Assens, 2021-05-06



Regulatory Affairs and Quality Assurance Manager