

**CE DECLARATION OF CONFORMITY****Plum 0.9% Sodium chloride eyewash****Eye irrigation fluid for first aid**

We, the manufacturer, of the family of products covered by this declaration, hereby declare that the bottles/ampoules with sterile irrigation fluid listed below, meet the essential requirements set forth in Annex I of 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 A/S is responsible for Declaration of Conformity concerning medical devices as amended:

Item Name
200 ml Plum 0.9% NaCl Eyewash
500 ml Plum 0.9% NaCl Eyewash
1000 ml Plum 0.9% NaCl Eyewash
500 ml Plum 0.9% NaCl Eyewash DUO
1000 ml Plum 0.9% NaCl Eyewash DUO
20 ml Ampoule Plum 0.9% NaCl Eyewash

With the Intended use:

The Plum 0.9% Sodium chloride eyewash solution is to be used as a first aid product for eye irrigation.

We guarantee and declare that

1. The devices is a Class Is according to Annex IX, rule 5.
2. The irrigation fluid is STERILE
3. The planning and manufacture procedure is 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 Presafe Denmark A/S (ID No. 0543) certifies Plum A/S.  
The latest EC Certificate No. DGM-272.1.

Assens, 2018-03-09

Plum A/S



Lise S Bollen

Quality Manager