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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/ampoules 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 A/S 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	20 mL
4691	Plum Eyewash 0.9% Sodium Chloride	200 mL
4604	Plum Eyewash 0.9% Sodium Chloride	500 mL
4707	Plum Eyewash 0.9% Sodium Chloride	1000 mL
4861	Plum Eyewash 0.9% Sodium Chloride DUO	500 mL
4800	Plum Eyewash 0.9% Sodium Chloride DUO	1000 mL

With the intended use:

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 Presafe Denmark A/S (ID No. 0543) certifies Plum A/S.
The latest EC Certificate No. DGM-272 2019-12-03.

Assens, 2020-04-29
Plum A/S

Lise S Bollen
Quality Manager