

## CE DECLARATION OF CONFORMITY

### Neutralizing emergency shower and eye irrigation fluid for first aid

supplied to

**Kroschke**

We, the manufacturer of the products covered by this declaration, hereby declare that the bottles with sterile irrigation fluid, which are part of the above mentioned product group, and which are part of the products listed below, meet the essential requirements set forth in Annex I of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended:

Item Number	Item Name	GMDN code
<b>0.9% Sodium chloride solution</b>		
4624	200 ml Eye Wash	11655
4625	500 ml Eye Wash	11655
47071	1000 ml Eye Wash	11655
48611	500 Eye Wash DUO	11655
48001	1000 ml Eye Wash DUO	11655
<b>4.9% Phosphate buffer solution</b>		
4754	200 ml Neutralizing Eye Wash	11655
48011	500 ml Neutralizing Eye Wash DUO	11655

We guarantee and declare that

1. The devices satisfy the applicable provisions of Council Directive 93/42/EEC and its Danish implementation.
2. The devices are to be considered as Class Is according to Annex IX, rule 5.
3. The devices are marketed in STERILE packing
4. 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 as well as in compliance with the requirements of EN ISO 13485.

Plum A/S is certified by the notified body Presafe Denmark A/S (ID No. 0543).  
 The latest EC Certificate No. DGM-272.1.

Assens, 2016-08-08

Plum A/S



Lise S Bollen

Quality Manager