

Plum A/S Frederik Plums Vej 2 DK-5610 Assens Tel.+45 6471 2112 Fax+45 6471 2125 plum@plum.dk www.plum.dk

CE DECLARATION OF CONFORMITY

Eye irrigation fluid for first aid

We, the manufacturer, hereby declare that the bottles 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 concerning medical devices as amended:

Item Number	Item Name
46043	500 ml Eye Wash ACME Europe
46913	200 ml Eye Wash ACME Europe
47530	200 ml pH Neutral ACME Europe
47879	500 ml Eye Wash/ 200 ml pH Neutral ACME Europe
51601	QuickRinse ACME Europe

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.

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

Assens, 2016-01-08

Plum A/S

Lise S Bollen Quality Manager



Plum A/S Frederik Plums Vej 2 DK-5610 Assens Tel.+45 6471 2112 Fax+45 6471 2125 plum@plum.dk www.plum.dk

CE DECLARATION OF CONFORMITY

Plasters products

We, the manufacturer of the products covered by this declaration, hereby declare that the plasters 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 No	Item Name	
55017	QuickAid Spender Water ACME Europa	
55027	QuickAid Spender Elastic ACME Europa	
55037	QuickAid Spender Detectable ACME Europa	
55084	QuickAid Refill Elastic Long ACME Europa	
55119	QuickAid Refill Water ACME Europa	
55129	QuickAid Refill Elastic ACME Europa	
55139	QuickAid Refill Detectable ACME Europa	

We guarantee and declare that

- 5. The devices satisfy the applicable provisions of Council Directive 93/42/EEC and its Danish implementation.
- 6. The plasters are to be considered as Class I according to Annex IX, rule 4.
- 7. 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.

Assens, 2016-01-08

Plum A/S

Lise Bollen Quality Manager