

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

CE DECLARATION OF CONFORMITY

Plum Eyewash pH Neutral 4.9% Phosphate

Eye irrigation fluid for first aid

We, the manufacturer, of the products covered by this declaration, hereby declare, that the bottles with the 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
4752	Plum Eyewash pH Neutral 4.9% Phosphate	200ml
4801	Plum Eyewash pH Neutral 4.9% Phosphate DUO	500ml

With the intended purpose:

Plum Eyewash pH Neutral 4.9% Phosphate is to be used as a first aid product for eye irrigation involving accidents with acids and alkali.

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, 2023-03-28



Regulatory Affairs and Quality Assurance Manager

Declaration of Conformity

Manufacturer AKLA AB
(Enhagsslingan 2)
Box 534
SE-182 15 Danderyd

Plum QuickCool Burn Gel (955430)

REF: 94370 FOR BURNS Burn Gel 3,5 gram

Classification: Class IIa Rule 4.

FOR BURNS gel is a first aid product for burns. It is intended to be used with small burns. It is not being intended for burns and wounds requiring healing by secondary intent.

We hereby declare that the above mentioned devices comply with the Swedish legislation LVFS2003:11 transposing European Medical Devices Directive 93/42/EEC

EC certificate 41314724 valid to 2024-05-27 under the transition period to MDR2017/745

Täby 2021-02-24
AKLA AB



Eva Janmark
Managing Director

Postadress Mailing address	Besöksadress Visitors	Tel	Fabrik/Factory	Bank	Bankgiro	Postgiro
AKLA AB Box 534 SE-182 15 DANDERYD	Enhagsslingan 2 TÄBY Säte/Registered office TÄBY	+46(0)8 446 47 30 Fax +46(0)8 446 47 47	Parkgatan 15 SE-696 33 ASKERSUND Tel.. +46(0)583 71 11 35 Fax. +46(0)583 71 15 05	SEB Org.nr/VAT No SE556027643701	295-8049	1670-9

Declaration of Conformity

(Försäkran om överensstämmelse)

Manufacturer AKLA AB
(Enhagslingan 2)
Box 534
SE-182 15 Danderyd
Sweden

REF: 92111 Plum QuickStop Wound Dressing (955440)

Classification Class I Sterile, Rule 4

First Aid products for wounds.

Intended to be used as a mechanical barrier and compression

We hereby declare that the above mentioned devices comply with the Swedish legislation LVFS2003:11 transposing European Medical Devices Directive 93/42/EEC

EC certificate 41310145 valid to 2024-05-26 under the transition period to MDR2017/745

Täby 2021-02-24

AKLA AB



Eva Janmark
Managing director

Declaration of Conformity

(Försäkran om överensstämmelse)

Manufacturer AKLA AB
(Enhagslingan 2)
Box 534
SE-182 15 Danderyd
Sweden

REF: 92109 Plum QuickStop Wound Dressing (955441)

Classification Class I Sterile, Rule 4

First Aid products for wounds.

Intended to be used as a mechanical barrier and compression

We hereby declare that the above mentioned devices comply with the Swedish legislation LVFS2003:11 transposing European Medical Devices Directive 93/42/EEC

EC certificate 41310145 valid to 2024-05-26 under the transition period to MDR2017/745

Täby 2021-02-24

AKLA AB



Eva Janmark
Managing director

Declaration of Conformity

(Försäkran om överensstämmelse)

Manufacturer *AKLA AB*
 (Enhagsslingan 2)
 Box 534
 182 15 Danderyd
 Sweden

Plum Quick Clean (955422A)

REF: 94407ST Wash swab

We hereby declare that the above mentioned devices comply with the Swedish legislation LVFS2003:11 transposing European Medical Devices Directive 93/42/EEC.

Product Class Is, Rule 1.

Intended use: Swab for cleansing of minor wounds.

EC certificate 41310145 valid to 2024-05-26 under the transition period to MDR2017/745

Täby 2021-03-01
AKLA AB



Eva Janmark
Managing Director

