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

Mandelalléen 1 • 5610 Assens Denmark • Tel. +45 6916 9600 • info@plum.eu • www.plum.eu

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 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
4747	Plum Eyewash pH Neutral 4.9% Phosphate	500ml
4746	Plum Eyewash pH Neutral 4.9% Phosphate Shower	1000 ml
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, 2021-05-06

Regulatory Affairs and Quality Assurance Manager

Mandelalléen 1 • 5610 Assens Denmark • Tel. +45 6916 9600 • info@plum.eu • www.plum.eu

EU Declaration of Conformity

Manufacturer:	Plum Safety ApS Mandelalléen 1, 5610 Assens Denmark
SRN (Single Registration Number):	DK-MF-000008672
Name of the product:	Plum QuickFix plasters

Reference number:

Art No	Art Name
5511	Plum QuickFix Water resistant
5512	Plum QuickFix Elastic
5508	Plum QuickFix Elastic Long
5504	Plum QuickFix Elastic Mini
5518	Plum QuickFix Elastic Micro
5513	Plum QuickFix Detectable
5509	Plum QuickFix Detectable long
5515	Plum QuickFix Alu
5519	Plum QuickFix Alu Micro

Intended purpose:	Plum QuickFix plasters are used as a first aid product as mechanical barrier and for absorption of exudates.
Basic UDI-DI:	5715205QFPLASTER01SS
Device classification:	Class I, according to Annex VIII, Rule 4

This declaration of conformity is issued under the sole responsibility of Plum Safety ApS. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by Presafe Denmark A/S, Certificate No.: DGM-940.

All supporting documentation is retained at the premises of the manufacturer.

The medical devices comply with the state-of-the-art requirements referred to in the standards mentioned in the current edition of the Technical Documentation.

Reference to common specifications: Not Applicable

Signature for Plum Safety ApS:

Place and date:
Assens, 2023-03-28

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Katarzyna Luiza Grzych
Person Responsible for Regulatory Compliance

AKLA
First Aid System

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 adress	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

AKLA
First Aid System

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

AKLA
First Aid System

Declaration of Conformity

(Försäkran om överensstämmelse)

Manufacturer ***AKLA AB***
(Enhagsslingan 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

AKLA
First Aid System

Declaration of Conformity

(Försäkran om överensstämmelse)

Manufacturer ***AKLA AB***
(Enhagsslingan 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

AKLA
First Aid System

Declaration of Conformity

Manufacturer ***AKLA AB***
Enhagsslingan 2
SE-18740 Täby
Sweden

REF. No	***Description***	***Size***	***Risk Class***
REF 94373	*Burn and Wound dressing*	*10x10cm*	*Class IIb Rule 4. Sterile*

The dressings are first aid products for burns injuries and wounds.
It is intended to be used with burns which have breached the dermis and can only heal by secondary intent.

We hereby declare that the above mentioned devices comply with the European Medical Devices Directive 93/42/EEC.

Notified Body
Intertek 0413

EC certificate 41314724-02 valid to 2024-05-27 under the transition period to MDR2017/745.

Täby 2022-08-29
AKLA AB

Eva Janmark
Managing Director

AKLA
First Aid System

Declaration of Conformity

Manufacturer *AKLA AB*
Enhagsslingan 2
SE-18740 Täby, Sweden

SRN (Single Registration Number): SE-MF-000004567

First Aid products for wounds. Classification Class I Sterile, Rule 4.

Intended use: As a mechanical barrier and compression.

REF: 92109	Pull1Aid Blood Stopper Mini (compress), *First Aid bandage*	*7,5 x 12 cm*
REF: 92111PM	Pull1Aid Blood Stopper (compress), *First Aid bandage*	*17 x 17 cm*

We hereby declare that the above-mentioned devices comply with the European Medical Devices Directive 93/42/EEC

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

Notified Body
Intertek, 0413

Täby 2022-08-29
AKLA AB

Eva Janmark
Managing director

EU Declaration of Conformity

Manufacturer: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)

Address: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech EcologicalPark, Panyu, 511400 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

SRN: Not available yet

European Representative: MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: CPR Face Shield
Product Name: CPR Face Shield
Product code: FS-100,FS-101,FS-102,FS-103,FS-105,FS-106

Applied Standard & Common Specification:	EN ISO 14971:2019
Basic UID:	Not available yet
Classification acc. to MDR Ax .VIII:	Class I, Rule 1
Conformity assessment procedure:	Annex II +Annex III of MDR

CE certificate No:	N.A
Name and ID of the Notified Body:	N.A

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Signature Janice-Li

Name: Janice-Li

Position: MR

Place: Guangzhou

Date: 2021.6.2