

Company Name & Address

Amsino International, Inc.
708 Corporate Center Drive
Pomona, CA 91768 USA

Manufacturing Site

Amsino Healthcare (USA), Inc.
330 Corporate Woods Parkway
Vernon Hills, IL 60061 USA

European Authorized Representative

EMERGO EUROPE B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Product Category:

Water and saline solutions for inhalation (reference Attachment 1)

Classification: IIa

Conformity Assessment Route: Annex V

We hereby to certify that the above-mentioned product(s) conform to the essential requirements of Council Directive 93/42 EEC and all the EN harmonized standards.

Directive& Standards:

All applicable harmonized standards (published in the official Journal of the European Communities) and Council Directive 93/42 EEC.

Notified Body:

MedCert GmbH
Pilatuspool 2
20355 Hamburg, Germany
Notified body № 0482

CE certificate No.: 2708GB414190221

By: 
Gayane Keshishyan, Senior Quality Technician
Amsino Healthcare (USA), Inc.

Date: 15 OCT 2019

Attachment 1

Number	Catalog №	Product Description	EU Risk Class	EU Rule
1	AS0352	Sterile Water for Inhalation USP 350 mL Humidifier Bottle	IIa	5
2	AS0552	Sterile Water for Inhalation USP 550 mL Humidifier Bottle	IIa	5
3	AS1065	Sterile Water for Inhalation USP 1000 mL Pour Bottle	IIa	5
4	ASR0039	Sodium Chloride Inhalation Solution USP (0.9% NaCl) 3 mL Unit Dose Vial	IIa	5
5	ASR0059	Sodium Chloride Inhalation Solution USP (0.9% NaCl) 5 mL Unit Dose Vial	IIa	5
6	ASR0159	Sodium Chloride Inhalation Solution USP (0.9% NaCl) 15 mL Unit Dose Vial	IIa	5
7	0352	Sterile Water for Inhalation USP 350 mL Humidifier Bottle	IIa	5
8	0552	Sterile Water for Inhalation USP 550 mL Humidifier Bottle	IIa	5
9	1065	Sterile Water for Inhalation USP 1000 mL Pour Bottle	IIa	5
10	R0039	Sodium Chloride Inhalation Solution USP (0.9% NaCl) 3 mL Unit Dose Vial	IIa	5
11	R0059	Sodium Chloride Inhalation Solution USP (0.9% NaCl) 5 mL Unit Dose Vial	IIa	5
12	R0159	Sodium Chloride Inhalation Solution USP (0.9% NaCl) 15 mL Unit Dose Vial	IIa	5