

**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, Quality Supervisor

Amsino Healthcare (USA), Inc.

Date: \_\_\_\_\_



**Attachment 1**

| Number | Catalog № | Product Description                                                         | EU Risk Class | EU Rule |
|--------|-----------|-----------------------------------------------------------------------------|---------------|---------|
| 1      | AS0352E   | Sterile Water for Inhalation USP<br>350 mL Humidifier Bottle                | IIa           | 5       |
| 2      | AS0552E   | Sterile Water for Inhalation USP<br>550 mL humidifier Bottle                | IIa           | 5       |
| 3      | AS1065E   | Sterile Water for Inhalation<br>1000 mL Bottle                              | IIa           | 5       |
| 4      | AS1565E   | Sterile Water for Inhalation USP<br>500 mL Pour Bottle                      | IIa           | 5       |
| 5      | AS1765E   | Sterile Water for Inhalation USP<br>750 mL Pour Bottle                      | IIa           | 5       |
| 6      | ASR0035E  | Sterile Water for Inhalation USP<br>3 mL Unit Dose Vial                     | IIa           | 5       |
| 7      | ASR0055E  | Sterile Water for Inhalation USP<br>5 mL Unit Dose Vial                     | IIa           | 5       |
| 8      | ASR0039E  | Sodium Chloride Inhalation Solution USP (0.9% NaCl)<br>3 mL Unit Dose Vial  | IIa           | 5       |
| 9      | ASR0059E  | Sodium Chloride Inhalation Solution USP (0.9% NaCl)<br>5 mL Unit Dose Vial  | IIa           | 5       |
| 10     | ASR0159E  | Sodium Chloride Inhalation Solution USP (0.9% NaCl)<br>15 mL Unit Dose Vial | IIa           | 5       |