

# **EC-Certificate of Conformity**

### The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Amsino Healthcare (USA), Inc. 330 Corporate Woods Parkway Vernon Hills, IL 60061-3107 USA

has introduced, applies and maintains a Quality Assurance System for the products / product categories:

Water and saline solutions for inhalation

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex V

The license of certification is subject to surveillance by MEDCERT.

#### This certificate is valid until: 07 July 2023

Report No.: 2708FS22F Process No.: QS – 2708 Certificate No.: 2708GB414190221

Hamburg, 21 February 2019

**MEDCERT** Certification Body (Dr. Andreas Schich)

#### MEDCERT Identification No.: 0482



Benannt durch/Designated by Zentralstelle der Länder & für Gesundheitsschutz & bei Arzneimitteh und Medizinprodukten & ZLG-BS-237.10.15