

CERTIFICATE

Certificate Registration No. PS.NA.15.014

15 September, 2015

Dry Salt Aerosol Generator

HaloSmart-01

 Made by: "Halomed" UAB
 Savanoriu av. 65 A, LT-03149 Vilnius, Lithuania

Conforms to the requirements of the standards:

LST EN 61010-1:2011(IEC 61010-1:2010)
EN 55014-1:2006/A1:2009
EN 55014-2:1997/A1:2001
EN 55014-2:1997/A2:2008.

This certificate is issued on the base of:

Test Reports: No. 03-11S, No. 05-13S and No.04-14S issued by Testing Laboratory of Certification Center "Sertika", Ltd. No. 29.1 PB-53 issued by Equipment and Devices Electromagnetic Compatibility Control Division of Communications Regulatory Authority (Lithuania).

Certification was based on the A certification scheme.

This certificate gives the right to mark the certified product with the SERTIKA conformity mark.

This certificate is valid up to 27 June, 2016.

Director



Ingrida Kusiene

 Certification Center "Sertika" Ltd.
 Savanoriu av. 271 - 253, LT-50131 Kaunas, Lithuania

 sertika@sertika.lt
 www.sertika.lt

CERTIFICATE OF ANALYSIS

Laboratory Salinen Austria AG

"PHARMASAL" - Chemically Pure Salt
 Sodium Chloride for pharmaceutical use, Natrii chloridum
 according to European Pharmacopoeia, BP, USP, JP

Lot number CRS130815
Retest date 13.08.2018
Production date 13.08.15 - 18.08.15

	Specification	Unit	Result	Unit
Identification	Na ⁺	positive	conforms	-
Identification	Cl ⁻	positive	conforms	-
Assay	NaCl	99,5 - 100,5	%	99,95
Bromides	Br ⁻	<= 100	ppm	<= 100
Iodides	I ⁻	<= 10	ppm	<= 10
Sulphates	SO ₄ ²⁻	<= 200	ppm	<= 200
Phosphates	PO ₄ ³⁻	<= 25	ppm	<= 25
Nitrites	NO ₂ ⁻	<= 0,01	A	<= 0,01
Heavy metals	as Pb	<= 3	ppm	<= 3
Iron	Fe	<= 2	ppm	<= 2
Aluminium	Al	<= 0,2	ppm	<= 0,2
Arsenic	As	<= 1	ppm	<= 1
Potassium	K	<= 500	ppm	<= 500
Barium	Ba	<= 10	ppm	<= 10
Magnesium and alkaline-earth metals	calc. as Ca	<=100	ppm	<=100
Ferrocyanides	[Fe(CN) ₆] ⁴⁻		conforms	-
Insoluble matters		<= 50	ppm	<= 50
Loss on drying		<= 0,5	%	<= 0,5
Appearance of solution		clear, colourless	conforms	-
Acidity or Alkalinity according to the regulations		conforms	conforms	-
Residual Solvents (according ICH-guideline)		Impossible due to production process	conforms	-
Bacterial Endotoxins		< 5,0	I.U./g	conforms
TAMC		<= 10	CFU/g	conforms
TYMC		<= 10	CFU/g	conforms

 This lot conforms with the current Ph. Eur, USP, BP and JP monographs. In compliance with the guidelines on good manufacturing practice for active pharmaceutical ingredients (ICH Q7).
 Store in a clean and dry place, nmt. 70% rel. Humidity.

 Qualified Person
 Dipl.-Ing. Birgit Spreitz
 Date: 2015-09-27

Salinen Austria AG
 Steinkogelstraße 30
 A-4802 Ebensee
 Tel. 06132 / 209-0
 Fax 06132 / 200-4100



CERTIFICATE

Certificate Registration No. PS.NA.15.015

15 September, 2015

Dry Salt Aerosol Generator

HaloCompact

 Made by "Halomed" UAB
 Savanoriu av. 65 A, LT-03149 Vilnius, Lithuania

Conforms to the requirements of the standards:

LST EN 61010-1:2011(IEC 61010-1:2010)
EN 55014-1:2006/A1:2009
EN 55014-2:1997/A1:2001
EN 55014-2:1997/A2:2008.

This certificate is issued on the base of:

Test Reports: No. 03-13S, and No.02-14S issued by Testing Laboratory of Certification Center "Sertika", Ltd. No. 29.1 PB-188 issued by Equipment and Devices Electromagnetic Compatibility Control Division of Communications Regulatory Authority (Lithuania).

Certification was based on the A certification scheme.

This certificate gives the right to mark the certified product with the SERTIKA conformity mark.

This certificate is valid up to 13 February, 2016.

Director



Ingrida Kusiene

 Certification Center "Sertika" Ltd.
 Savanoriu av. 271 - 253, LT-50131 Kaunas, Lithuania

 sertika@sertika.lt
 www.sertika.lt

CE DICHIARAZIONE DI CONFORMITA

Noi, fabbricante, la società "HALOMED", Ltd.,

indirizzo: Savanoriu pr. 176, LT- 03154 Vilnius, Lithuania,

Dichiariamo, sotto la nostra responsabilità che il dispositivo:

Nome del prodotto: DISPOSITIVO DI AEROSOL DI SALE
 HALOGENERATORE,
 destinato per lo scopo delle procedure di benessere

Modello/Tipo: HaloCompact

CONFORME AI REQUISITI DELLE DIRETTIVE:

2006/95/CE del Parlamento Europeo e del Consiglio, del 12 dicembre 2006 concernente la armonizzazione delle legislazioni degli Stati Membri relative al materiale elettrico destinato ad essere adoperato entro l'faluni limiti di tensione

e

2004/108/CE del Parlamento europeo e del Consiglio, del 15 dicembre 2004, concernente il ravvicinamento delle legislazioni degli Stati Membri relative alla compatibilità elettromagnetica.



 direttore  Arkadijus Kolisovas

Vilnius, 2015