1. HaloCompact-01+SKÉ







2. HaloVita





3. HaloSet+SKÉ





4. HaloPrima-03 Mini+SKÉ





EC Certificate No. 1434-MDD-252/2020 Production Quality Assurance Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies that the quality assurance system in the organization:

HALOMED UAB

Fabijoniskiu g. 41-99 LT-07119 Vilnius, Lithuania

for manufacture and final inspection of medical devices, class IIa

Salt Aerosol Generator HaloPrima-03 Mini

of Annex V to Directive 93/42/EEC (as amended) implemented into Polish law as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 04.06.2020 to 31.08.2022 The date of issue of the Certificate: 04.06.2020 The date of the first issue of the Certificate: 01.09.2017



Anna felinolaria polposi pice Ana Malgorzata solgozaniento feli zione estre Myroba feli zione estre Myroba Vice-President

5. HaloSet ver.2.1.1.-SKÉ





6. HaloSet ver.2.2.1.-SKÉ





7., 8. HaloSPA-03 (+SKÉ) (régi nevén HaloPrima-01)





CERTIFICATE

SALT AEROSOL GENERATOR HaloSPA-03

Manufacturer UAB HALOMED ių av. 65A, LT-03149 Vilnius, Lithuania

Conforms to the requirements of the standards: LST EN 61010-1:2011 (IEC 61010-1:2010) EN 60601-1-2:2015

Test reports No. 03-145 and 13-145, issued by UAB SERTIKA testing laboratory.
Test Report No. (29.1) P8-106 (2018-08-21), issued by Equipment and Devices ctromagnetic Compatibility Control Division of Communications Regulatory Authority (Lithuania)



9. HaloPrima-02 M+SKÉ





Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies, that the quality assurance system in the organization:

HALOMED UAB

Fabijoniškių str. 41-99, LT-07119 Vilnius, Lithuania

for manufacturing and final inspection of medical devices class IIa

Salt Aerosol Generator HaloPrima-02M

complies with requirements of Annex V to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 24-09-2018 to 23-09-2023 The date of issue of the Certificate: 24-09-2018 The date of the first issue of the Certificate: 24-09-2015



10. HaloSmart-01+SKÉ





CERTIFICATE

Certificate Registration No. PS.21.002 23rd of March, 2021

Dry Salt Aerosol Generator

HaloSmart-01

Manufacturer HALOMED, UAB
Business address: Savanorių Ave. 65A, LT03149 Vilnius, Lithuania
Registered address: Fabijoniškių Str. 41-99, LT-07119 Vilnius, Lithuania

Conforms to the requirements of the standards:

EN 61010-1:2011 (IEC 61010-1:2010) EN 55014-1:2006/A1:2009

Certificate is issued on the base of:
Test report No. 04-145 and 24-16K, Issued by UAB SERTIKA testing laboratory.
Test Report No. (92.) 198-53 issued by Equipment and Devices Electromagnetic
Compatibility Control Division of Communications Regulatory Authority (Lihuania)

Certification was based on the A certification scheme.

This certificate is valid up to 22nd of March, 2024

Director Ingrida Kusienė Huyy