

DECLARATION OF CONFORMITY



Manufacturer: TEHNO BIONIC SRL
55 Agriculturii Street, 120055, Buzău - Romania
SRN : RO-MF-000021063

We, TEHNO BIONIC SRL declare under the sole responsibility that the product specified bellow:

Product name: DRY SALT INHALER
Brand: SaltMed
Risk class: IIa (Annex IX, Rule 11)
UDI – DI Basic 59447590625944759062SM1XK (GMN)
Air Pump Serial No.:....., Cartridge Type .. ; LOT No.:

Comply with the provisions of Annex I of Directive 93/42/EC – Essential Requirements

Conformity assessment procedure: Annex V, VII to Directive 93/42/EC concerning medical devices.

BUREAU VERITAS ITALY SPA, NB 1370 conducted Conformity Assessment and issued Certificate of Conformity No.: IT 266961- 2/20.02.2020.

List of applicable harmonized standards:

EN ISO 13485:2016	EN 60601-1-2:2015
EN ISO 14971:2012	EN 60601-1-6:2010
EN 60601-1:2006 + A1:2013	EN 60601-1-11:2015

Name: Constantin Pascu
Signature

Place and date:

Buzău