

Personal perineal probe for the treatment of incontinence
by electro stimulation and biofeedback (EMG and/or pressure)
for professional and/or home use.



Carefully read this document before using the device!

Instructions for use of PERIPROBE / PERISPHERA® vaginal probes

The probe must be used only with the electrotherapy (and/or biofeedback) Medical Devices (MD) characterised by: **Symmetrical biphasic pulses, with zero mean value (zero DC); Maximum current 50 mA_{RMS} - Maximum voltage ± 80 V (160 Vpp); Maximum frequency: 200Hz with maximum impulse of 500 μ s.** The personal use probe, **must not** be sterilized; sterilization may damage the Medical Device. On first use, the bag containing the probe must be sealed. The probe is packaged in a **non-sterile** package, however it is disinfected before packaging. Before using the probe for the first time, it must be cleaned with water to remove any traces of disinfectant. **DO NOT** immerse the probe in any liquid, the probe must be cleaned only with a cloth soaked in water and possibly neutral soap even after each use and must be stored dry, in its own resealable bag. The probe must be kept away from sulphur or sulphured substances, which could damage the appearance of the gold-coated electrodes. Insert the probe into the vaginal orifice only after connecting it to the Electro therapy and/or Biofeedback Medical Device. In case of difficulty in insertion or poor electrical conduction, slightly moisten the probe or use a small amount of water-based gel; **avoid** joint use with medicines. Start therapy by referring to the user manual of the medical device connected to the probe.

CONTRAINDICATIONS - Do not use the electro stimulation probe in the case of known or suspected situations: bladder, vaginal or anal infections • colorectal or genitourinary tumours • pregnancy • pacemaker carriers (consult the doctor who prescribed the pacemaker) • vesicoureteral reflux • hypotonic bladder • anatomical modifications of the vaginal access that may prevent or make it difficult to insert the probe • abnormal bleeding or bleeding outside the menstrual period.

WARNING! ❖ This manual and packaging are part of the medical device ❖ **DO NOT** rotate or disassemble the parts of the probe ❖ The long-term effects of perineal stimulation are not yet determined ❖ Scrupulously observe the instructions of the specialist medical prescription ❖ Do not connect the probe to an electro-scalpel (risk of burns) ❖ Do not use the probe if the electrodes are damaged ❖ Patients and users shall be required to report any serious incidents involving the device, to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

WARRANTY - This product is a so-called consumable medical device and as such subject to deterioration; the MD is tested to be used for a maximum of about 60 sessions (max 1 hour per session). The warranty on the product is provided for a maximum period of six months from the date of purchase and in any case guarantees functionality for a limited use of approximately 60 sessions. To obtain the verification and/or replacement of the product and activate the warranty, the consumer must send it to the retailer or to the manufacturer, with the original packaging, bag or box with the batch number, including all accessories that may be provided and all useful contact information so that the user can be contacted in the case of need.

