The undersigned con C.F. DLSCRL71L01H501P, on behalf of DONAWA LIFESCIENCE CONSULTING SRL, delegated by the Manufacturer or by the Agent to register data pertaining
to the medical devices stated below, has validated the following information:

****

System progressive:2255592
Validated on: 19/05/2022
Trade name and model: XCITE CLINICAL STATION
FA216218
Additional trade names:
- XCITE 2
Code assigned by the manufacturer (catalogue identifier): FA216218
Role of the user entering the DM: ALTRO SOGGETTO DELEGATO DAL FABBRICANTE
Manufacturer: RESTORATIVE THERAPIES, INC
Agent: EMERGO EUROPE
CND Classification: SISTEMI PER STIMOLAZIONE ELETTRICA FUNZIONALE - ALTRA
Complete GMDN repertoire: An assembly of mains electricity (AC-powered) devices used to apply various modes of electrical stimulation transcutaneously to treat/prevent neuromuscular symptoms and disorders typically as a form of physical therapy. It typically includes an electric current pulse generator, electrodes/probes, audible and/or visual displays, and software. It may provide biofeedback and/or transcutaneous electrical nerve stimulation (TENS) to treat pain. It is typically used to prevent muscle atrophy, for muscle re-education, to relax muscle spasms, to improve blood circulation, for post-surgical calf muscle stimulation to prevent venous thrombosis, and/or to maintain or increase range of motion.
EC Classification: Classe IIa (D.L.vo 46/97 attuazione Dir. CE 93/42)
Annex according to which the device was marked: Annex V Annex VII

****

The information was successfully acquired by the Ministry of Health issued the following id notification to use for subsequent communications:

The undersigned states he/she is aware of the sanctions provided for in case of false statement (art.76 of the D.P.R. n. 445 dated 28.12.2000).