EU Declaration of Conformity

For the following equipment:

Product Description	Product Name / Model	
Low Frequency Therapeutic Device	HD TENS / EMS	HD2 HD4P / EM 80
	SL TENS / EMS	SL-880 / EM 49 / EM 59 SL-884 / SEM 44 / EM 89 SL-880H
	pennypad	PP-909 / PP-909K / PP-919 / EM 10 / EM 50 / EM 55 FT-610 FT-810
	painpad	SP-610
	EP TENS	EP-300

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance the essential requirement – Annex I and the conformity assessment Annex II-exclusive section 4 to be certified by DNV GL PRESAFE AS (Veritasveien 3, N-1363 Høvik, Norway, notify body number – 2460) for the evaluation regarding the Class IIa product safety aspects.

The following European Authorized Representative is stated to the declaration:

HIVOX BIOTEK B.V. / De Run 4428, 5503 LR Veldhoven, Netherland

(Company Name/Address)

The following person is solely responsible for the compliance of declaration:

HIVOX BIOTEK INC. / 5F., No. 123, Xingde Rd., Sanchong Dist., New Taipei City, Taiwan, R.O.C.

(Manufacturer Name/Address)

Marx Lee / Regulatory Affairs Manager	Marx Lee	2020.03.04
(Name/Position)	(Legal Signature)	(Date)