

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10435-2017-CE-RGC-NA-PS Rev 1.0

Project No.:
PRJC-36280-2007-PRC-RGC

Valid Until:
27 May 2024

This is to certify that the quality system of:

HIVOX BIOTEK INC.

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

For design, production and final product inspection/testing of:
ELECTRO-THERAPEUTIC MEDICAL DEVICE

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 22 April 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see
www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replace the certificate 54380-2009-CE-RGC-NA 2.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) issued	2017-06-13
1.0	Recertification, remove Snore Stopper, Dreamate, model AW-300/HD4/HD MINI/SL-882/CT3 and add model (Bold)	2020-02-22

Products covered by this Certificate:

Product Description	Product Name / Model		Class
Low Frequency Therapeutic Device	HD TENS/EMS	HD2	IIa
		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	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Hivox Biotek Inc.	5F., No. 123, Xingde Rd., Sanchong Dist., New Taipei City, Taiwan, R.O.C.
Hivox Electronics Co., Ltd.	No. 11, Donghuan Sec. Rd., Huangjiang Town, Dongguan City, Guangdong Prov. 523757, P.R.C.

EU Representative

Hivox Biotek B.V., De Run 4428, 5503 LR, Veldhoven, Netherlands

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate