元勛國際股份有限公司
DIGIMAX INNOVATIVE PRODUCTS LTD.

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Website : www.digimaxproducts.com

Declaration of Conformity

I, David Wu/CEO of DIGIMAX, hereby declare that the below mentioned medical device–

(i) Complies with all the requirements under the Act;

(ii) Has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) Conforms to requirements specified in Appendix 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of Medical Device

Generic Name:	Hearing Aid
Specified Name:	Hearing Aid
Brand / Model:	UP-6SXX, UP-6EXX (X=1~9, A~Z) (Refer to Appendix 1)
Manufacturer:	Digisine Energytech Co., Ltd.
Country of Origin:	Taiwan
Manufacturing Site:	4F., Bldg. B, No.248-26, Xinsheng Rd., Qianzhen Dist., Kaohsiung 806, Taiwan
Risk-based Classification:	Class B
Classification Rule:	Class IIa
GMDN Code:	N/A
Medical Device Registration Number (or any approval code):	CE 2460 FDA 3005053820 TFDA 007588 JFDA BG10600253

(B) Quality Management System Certificate ("QMS")

Conformity Assessment Body issuing the certificate:	ISO13485
Certificate Number:	239292-2017-AQ-TWN-NA-PS Rev. 3.0
Issuance Date:	10 July 2013
Expiry Date:	20 February 2025

(C) Standards Applied

Reference standard: BS EN ISO 14971:2012 (Refer to the Hearing Aid Risk Management Plan & Report)

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 15 July, 2019

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [*Act 737*] to make, sign, or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

M.S.D.N:0310947337 - C.T.C.P. CÔNG TY CỔ PHẦN THIẾT BỊ Y TẾ ÂU CHÂU QUẬN 1 - TP. HỒ CHÍ MINH

Nguyễn Hoàng Phương

Authorised Signatory:

Name: David Wu / Position: CEO

Date: 2022/2/9

Note:

(i) For Class B, Class C, and D medical devices, declaration of conformity to either of the following QMS standards is mandatory:
   (a) MS ISO 13485; or
   (b) Other quality management system standard recognised by the Medical Device Authority.

(ii) For Class A medical devices that are not manufactured under either of the above mentioned quality management system standards, certification obtained for alternative quality management system standards shall be listed in this section, if applicable.

(iii) For Class A medical devices with measuring function, conformity assessment certificate and calibration and metrology report, issue date, expiry date, calibration should be provided.

(iv) For Class A medical devices with sterilisation, validation report, and conformity assessment certificate number, issue date, expiry date should be provided.

The Declaration of Conformity, all document and certificates and attestations shall be duly certified true copy by the Applicant.