

APPENDIX 1A

Declaration of Conformity

POSTUREPALS PTY LTD
Law Partners House
Kumul Highway
Port Vila, Shefa
Vanuatu

DECLARATION OF CONFORMITY

I as representative from **POSTUREPALS PTY LTD**, 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: Biomechanical Tape
Specified name: Biomechanical Tape® Dynamic Tape
Brand/model: Dynamic Tape® / refer to attachment
Manufacturer: POSTUREPALS PTY LTD
Country of origin: China
Manufacturing site: SAILAISI (HANGZHOU) IMPORT&EXPORT CO., LTD.
No. 555, Xinken Road, Qianjin Street, Qiantang District,
Hangzhou, 311228 Zhejiang,
P.R. China

Risk-based classification: A
Classification rule: 4
GMDN code: NA
Medical device registration number or any approval code: Not Applicable

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

Conformity Assessment Body issuing the certificate: TUV Rheinland

Certificate number: SX 2156394-1

Issuance date: 15/03/2022

Expiry date: 30/01/2025

(C) Standards Applied

- EN ISO 13485:2016

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 12/06/2024.

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.

Authorised Signatory:



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Name:

Position: Director

Date: 12/06/2024

Attachment 1

Product List

NO	MEDICAL DEVICE NAME	PRODUCT CODE
	Dynamic Tape Original 5cm x 5m Beige/Beige Tattoo	DT50PL
	Dynamic Tape Original 5cm x 5m Beige/Black Tattoo	DT50TT
	Dynamic Tape Original 5cm x 31m Beige/Beige Tattoo	DT50PLB
	Dynamic Tape Original 5cm x 31m Beige/Black Tattoo	DT50TTB
	Dynamic Tape Original 7.5cm x 5m Beige/Beige Tattoo	DT75PL
	Dynamic Tape Original 7.5cm x 5m Beige/Black Tattoo	DT75TT