

DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:

Shenzhen Konmed Technology Co.,Ltd.
ADD: 601, Building B4, Shenchengtou
Creative Factory Life Science Park,
Julongshan A Road, Xiuxin Block Kengzi
Street, Pingshan District ,Shenzhen
Guangdong, CN 518118
SRN:CN-MF-000018375

EC Representative:

Shanghai International Holding Corp.
GmbH (Europe)
ADD: Eiffestrasse 80, 20537 Hamburg,
Germany
SRN: DE-AR-000000001

Name of device: TENS Electrode
Model: KM-824A, KM-824B, KM-826A, KM-826B,
KM-804, CS-0227S
UMDNS code: 11454
BASIC UDI-DI: /

Meet the provisions of Regulation (EU) 2017/745 which apply to it.

Classification: Class I
Rule: Rule 1,Annex VIII of the Regulation (EU) 2017/745.
Conformity Assessment Procedure: ANNEX II+III of Regulation (EU) 2017/745.

It bears the mark



The product concerned has been manufactured under a quality management system according to Art.10 of the Regulation (EU) 2017/745.

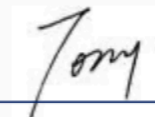
Following the procedure relating to the EU DECLARATION OF CONFORMITY set out in ANNEX IV of the Regulation (EU) 2017/745.

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

ISO 14971:2019
EN ISO 15223-1:2021
EN 1041:2008+A1:2013
EN ISO 10993-1:2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

ShenZhen 2021-04-21

Place, date

A handwritten signature in black ink, appearing to read 'Jomy', is written over a horizontal line.

GM

Legally binding signature, Function