

Shenzhen Kentro Medical Electronics Co., Ltd.	CE Technical File	File No	KTR20220113	Version	A1
	Declaration of Conformity	Effective Date	2022/01/13	Page	1 / 1

## DECLARATION OF CONFORMITY

### TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



MANUFACTURER: **Shenzhen Kentro Medical Electronics Co., Ltd.**

2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdong Province, China.

Medical Device: Electrode pads

Model: Fllow TENS pads and Arthro-Fllow pads

Classification - Annex IX: class I

We, Shenzhen Kentro Medical Electronics Co., Ltd., here with declare that the stated products meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices;

All supporting documentation is retained at the premises of the manufacturer.

Standards applied: 93/42/EE.

Identification number:



Certificate(s): ISO 13485



European Representative:

Wellkang Ltd

Enterprise Hub, NW Business Complex

1 Beraghmore Road, Derry, BT48 8SE

Northern Ireland

Start of CE-marking:

Place, Date of Declaration: China 2022-01-13

Signature:

*Zewu Zhang*

position: General Manager

name: Zewu Zhang