FysioTape

EC Declaration of Conformity

According to

Medical Device Regulation MDR 2017/745

MANUFACTURER	:	THYSOL HI-TECH LTD. (Ecoworkskorea) 17-40, Hwaseong-ro 1424, Gyeonggi-do, Seoul, South-Korea. SRN-number: KR-MF-000008975
EUROPEAN REPRESENTATIVE	:	FysioTape BV, Josink Kolkweg 18, 7545 PR, Enschede, The Netherlands SRN-number: NL-AR-000002061
PRODUCT NAME	:	Elastic balance tape
MODEL NAME + CODE	:	**CureTape ® Classic 5cm x 5m:** 1000, 1010, 1020, 1030, 1060, 1062, 1063, 1064, 1065 **CureTape ® Classic 1cm x 5m:** 1070-5, 1080-5 **CureTape ® Classic 2,5cm x 5m:** 1040-2 **CureTape ® Classic 7,5cm x 5m:** 1050 **CureTape ® Sports 5cm x 5m:** 2101, 2102, 2103, 2104, 2105 **CureTape ® Art 5cm x 5m:** 2201, 2202, 2203, 2204, 2205, 2206 **CureTape ® Punch 5cm x 5m:** 1200, 1210, 1220, 1230 **CureTape ® Giant 5cm x 5m:** 1001, 1011, 1021, 1031, 1061, 1066, 1067, 1068
CLASSIFICATION	:	Medical Device Class I, by rule 1 of annex 8, section III
Basic UDI:	:	87176241elastic-tapeWX

CE

This declaration of conformity is issued under the sole responsibility of FysioTape BV.
We hereby declare that the above mentioned products meet the provisions of the Medical Device Regulation MDR 2017/745. All supporting documentation is retained under the premises of the manufacturer.

Date of issue: July 2021

Place: Enschede, The Netherlands

Signature Manufacturer:	Signature European Representative:
Name: Hyunsuk Lee	Name: G.J. Olthoff
Function: President	Function: CEO