EC Declaration of Conformity

# EC Declaration of Conformity

**According to**

## Medical Device Directive MDR 2017/745

| | | |
|---|---|---|
| **Manufacturer** | : | **THYSOL ECOWORKS HITECH LTD**<br>**17-40 Hwaseong-ro, 1424 beon-gil, Namyang-eup, Hwaseong-si, Gyeonggi-do, South Korea** |
| **European Representative** | : | **THYSOL GROUP BV, Josink Kolkweg 18, 7545 PR, Enschede, The Netherlands** |
| **Product Name** | : | **Elastic-tape (basic UDI-DI: 871917226elastic-tapeY8)** |
| **Brand Name** | : | **CURETAPE Classic/Punch/Sports/Art/Beauty/Gentle, CROSSLINQ, PHYSIOTAPE, Dermaplast, Compex/Chatt tape** |
| **Classification** | : | **Class I by Rule 1 of Annex IX, MDR 2017/745** |
| **Conformity Assessment Route** | : | **Annex II, Exclusive Section 3, MDR 2017/745** |
| **SRN nr. EUDAMED** | : | **NL-AR-000000747 (THY) / KR-MF-000008975 (THY-HIT)** |

**Technical Construction File No.: EWK1201DC**

**We hereby declare that the above mentioned products meet the provisions of the Council Directive MDR 2017/745 for medical devices. All supporting documentation is retained under the premises of the manufacturer.**

CE

**The Declaration of Conformity is issued under the sole responsibility of THYSOL ECOWORKS HITECH LTD intended purpose**

**Start of CE-Marking : May 2021**

**Place, Date of Issue : Enschede, The Netherlands, 5th October 2021**

**Signature :** ----------

Peter Thissen, Managing Director THYSOL

THYSOL Group BV
Josink Kolkweg 18
7545 PR Enschede
The Netherlands
Tel: +31 53 2068040

ECOWORKS Korea
THYSOL HITECH Co, Ltd.,
17-40 Hwaseong-ro, 1424 beon-gil,
Namyang-eup, Hwaseong-si,
Gyeonggi-do, South Korea.