WETAPE Inc.
318 Jinwi-ro, Jinwi, Pyeongtaek, Gyeonggi-do 17711, Korea
Tel: 82-70-4711-7900 Fax: 82-31-662-1007

EC Declaration of Conformity

Manufacturer : WETAPE Inc..
318 Jinwi-ro, Jinwi, Pyeongtaek, Gyeonggi-do 17711, Korea
Manufacturer SRN no : KR-MF-000021188

European representative : TEJPY.cz s.r.o.
Pohnertova 1724/4, Kobylisy 182 00, Prague 8, Czech Republic

Product : BB Tape, KINESIOLOGY Tape, BB Cross tape, BB Face tape (Medical Tape Adhesive)

Classification : Class I by Rule 1 of Annex VIII, MDR 2017/745
Conformity Assessment Route : Annex IV, MDR 2017/745

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

Standards Applied
- Council Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- ISO 13485 [2003] Medical devices – Quality management system – Requirements for regulatory purposes
- ISO 14971 [2007] Medical devices-Application of risk management to medical devices
- ISO 10993-5 [2009]- Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10[2010]- Biological evaluation of medical device - Part 10: Tests for irritation and skin sensitization

Start of CE-marking : 2020.12.30

Place, Date of issue : Pyeongtaek, Korea. 2020.12.30

Signature :

CE

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President on behalf of
WETAPE Inc