Atex Co.,Ltd.
144 , Jangjisan-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, 10955, Korea
Tel : +82 31 948 6654 Fax +82 31 942 6182
Email : atexsales@atexmedical.com

EU Declaration of Conformity

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device that is covered by the present declaration is in conformity with regulation (EU) 2017/745 and specify other applicable union legislation.

Manufacturer

Name	:	Atex Co., Ltd
Address	:	144, Jangjisan-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, Republic of Korea Chungcheongbuk-do, Republic of Korea
Single Registration Number	:	KR-MF-000012358

EU Authorized Representative

Name	:	JaviTech e.K.
Address	:	Sachsenhausener Straße 16, 65824 Schwalbach am Taunus, Germany
Single Registration Number	:	DE-AR-000005875

Device

Product Name	:	Kinesiology Magnetic Tape
Brand Name	:	CureNetic Magnetic Patch
Model name	:	Coin Type, Cross Type, I Type, H Type
Basic UDI-DI	:	8809931361844CW
EMDN code	:	M030499 ELASTIC BANDAGES, SUPPORT AND COMPRESSION – OTHER
Intended Purpose	:	1) Reduce pain of muscle and joint - Create increased circulation and regeneration of blood, lymph, and tissue fluids which results in faster relief of muscle and joint pain 2) Prevent injuries (preventive practices) - Reduce overuse to protect weak muscles such as muscle stiffness and over-contraction - Prevent and reduce medical symptoms such as fascia syndrome, bruising, swelling, sprains, arthritis symptoms, edema, inflammation, carpal tunnel syndrome, plantar fasciitis, tendonitis - Improve neuromuscular feedback (called proprioception) that relaxes or facilitates stronger firing of muscles and tendons

Atex Co.,Ltd.
144 , Jangjisan-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, 10955, Korea
Tel : +82 31 948 6654 Fax +82 31 942 6182
Email : atexsales@atexmedical.com

3) Improve range of motion & Muscle re-education
- Improves kinesthetic awareness and sports performance by optimizing movements
- Adjust posture and reestablish muscle balance
- Maintain normal structural alignment
- Support injured areas or muscles & joints

Risk Class	:	Class I (Rule 1) according to Annex VIII of the regulation (EU) 2017/745
Applied Standards	:	Refer to Appendix I
Conformity Assessment Procedure	:	Annex II and III of the Regulation (EU) 2017/745

Place/Date: In Gyeonggi-do, Republic of Korea / on 2024-08-01

Name: Kim Hae Ryong
CEO of Atex Co., Ltd

Atex Co.,Ltd.
144 , Jangjisan-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, 10955, Korea
Tel : +82 31 948 6654 Fax +82 31 942 6182
Email : atexsales@atexmedical.com

Appendix I

Common specifications		
- There is no common specification relevant to the device		
Harmonised standards		
No.	**Standard**	**Description**
1	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices (ISO14971:2019)
3	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993 10:2021)
4	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
5	EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements (ISO 15223-1:2021)
Other solutions applied		
No.	**Standard**	**Description**
1	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
2	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
3	EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer (ISO 20417:2021)
4	CEN ISO/TR 24971:2020	Medical devices – Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
5	MDCG 2020-5	Clinical Evaluation – Equivalence
6	MDCG 2023-3	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices
7	MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
8	MEDDEV 2.12/1 rev.8	Guidelines on a Medical Devices Vigilance System