





Declaration of Conformity

Manufacturer Name	Medinox London Limited	
Manufacturer SRN	GB-MF-000009467	
Manufacturer Address	Solar House, 282 Chase Road, London, N14 6 NZ, United Kingdom.	
European Representative	Medinox Health Ireland Limited, Ground Floor, 71 Lower Baggot Street, Dublin D2, D02 P593, Ireland.	
European Representative SRN Number	IE-AR000006854	
Product UDI-DI	See Appendix A of this document	
BASIC- UDI-DI	505788179001EJ	
Product trade name	MX KINESIOLOGY TAPE FAMILY	
Product Code Number	See Appendix A of this document	
EMDN Code	M03040203	
Intended purpose	Adhesive tape	
Risk Class according to Annex VIII	Class I by rule 1.	
Statement that this device is in conformity with EU Regulation 2017/745	Certification by Article 52, Annex II and Annex III of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	
Reference standards	BS EN ISO 14971:2019	Medical Devices – Application of Risk management to Medical Devices
	BS EN 1041:2008+A1:2013	Information supplied by Manufacturer with medical Devices.
	BS EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
	BS EN ISO 10993-1:2018	Biological evaluation of Medical Devices.
	BS EN ISO 13485:2016	Medical devices. Quality management systems - Requirements for regulatory purposes.
	MEDDEV 2.7.1	Guidelines on Medical Devices / Clinical Evaluation: A guide for manufacturers and Notified Bodies
Notified Body Name	No notified body intervention is required.	
Description of conformity assessment of Notified body	No notified body intervention is required.	
Notified Body Certificate Identity	N/A	

Declaration of sole responsibility of this EU declaration	This declaration is issued under the sole responsibility of Medinox London Limited who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under the Medinox name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.
Date of issue	2021-06-04
Name of issuing officer	Mr J. J. Viljoen
Signature	
Designation	Senior Regulatory Officer
Signed on behalf of	Medinox London Limited
Company stamp	 <p>medinox[®] Medinox London Ltd Solar House, 282 Chase Road London N14 6NZ www.medinox.co.uk Company Number 11149212</p>

Appendix A

Product listings:

PROD CODE	DESCRIPTION	BARCODE	OUTER CASE BARCODE
MX79001	mx Kinesiology Tape - Cyan (5cm x 5m)	5057881790013	15057881790010
MX79011	mx Kinesiology Tape - Pink (5cm x 5m)	5057881790112	15057881790119
MX79021	mx Kinesiology Tape - Black (5cm x 5m)	5057881790211	15057881790218
MX79031	mx Kinesiology Tape - Blue (5cm x 5m)	5057881790310	15057881790317
MX79041	mx Kinesiology Tape - Beige / Nude (5cm x 5m)	5057881790419	15057881790416
MX79051	mx Kinesiology Tape - Yellow (5cm x 5m)	5057881790518	15057881790515
MX79061	mx Kinesiology Tape - Fuchsia (5cm x 5m)	5057881790617	15057881790614
MX79071	mx Kinesiology Tape - Dark Blue (5cm x 5cm)	5057881790716	15057881790713
MX79081	mx Kinesiology Tape - Camouflage (5cm x 5m)	5057881790815	15057881790812
MX79091	mx Kinesiology Tape - Reflective (5cm x 5cm)	5057881790914	15057881790911
MX79092	mx Kinesiology Tape - Red (5cm x 5cm)	5057881790921	15057881790928
MX79101	mx Kinesiology Tape – Camo Blue(5cm x 5m)	5057881791010	15057881791017
MX79111	mx Kinesiology Tape - Camo Green(5cm X 5cm)	5057881791119	15057881791116
MX79121	mx Kinesiology Tape - Camo Multi(5cm X 5cm)	5057881791218	15057881791215
MX79131	mx Kinesiology Tape - Camo Pink(5cm X 5cm)	5057881791317	15057881791314
MX79132	mx Kinesiology Tape - Red VP 5cm x 30m	5057881791324	15057881791321
MX79133	mx Kinesiology Tape - Nude VP 5cm x 30m	5057881791331	15057881791338
MX79134	mx Kinesiology Tape - Dark Blue VP 5cm x 30m	5057881791348	15057881791345
MX79135	mx Kinesiology Tape - Blue VP 5cm x 30m	5057881791355	15057881791352
MX79136	mx Kinesiology Tape - Black VP 5cm x 30m	5057881791362	15057881791369
OE80043	Kinesiology tape 5cm X5m Multicoloured Camo	5057881800439	15057881800436
OE80044	Kinesiology tape 5cm X5m Reflective	5057881800446	15057881800443
DYN- OE80045	Kinesiology tape 5cm x 5m Beige	5057881800453	15057881800450
OE80046	Kinesiology Kintape display	5057881800460	15057881800467
DYN- OE80047	Kinesiology tape 5cm x 5m Blue	5057881800477	15057881800474
DYN- OE80048	Kinesiology tape 5cm x 5m Black	5057881800484	15057881800481
OE80065	Kinesiology tape 5cm x 5m Camouflage Classic	5057881800651	15057881800658

Version control

Change	Date	Version Number
Replace the GMDN Code with the EMDN Code	10 th February 2022	1.2