





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	505788110201BT	
Product trade name	MX SUPPORTS FAMILY	
Product Code Number	See Appendix A of this document	
GMDN Code	41472	
Intended purpose	An external orthosis designed to support the hip, knee, ankle or foot. This is a reusable device.	
Risk Class according to Annex VIII	Class I by rule 1	
Statement that this device in in conformity with EU Regulation 2017/745	Certification by Article 53, 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	2021-09-28
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
VA10111	VAVIVO ELASTICATED KNEE SUPPORT -S	5057881101116	15057881101113
VA10121	VAVIVO ELASTICATED KNEE SUPPORT -M	5057881101215	15057881101212
VA10131	VAVIVO ELASTICATED KNEE SUPPORT -L	5057881101314	15057881101311
VA10141	VAVIVO ELASTICATED KNEE SUPPORT -XL	5057881101413	15057881101410
VA10151	VAVIVO ELASTICATED KNEE SUPPORT -XXL	5057881101512	15057881101519
VA10161	VAVIVO ELASTICATED KNEE SUPPORT -XXXL	5057881101611	15057881101618
MX10201	MX ELASTICATED KNEE SUPPORT WITH STAYS -S	5057881102014	15057881102011
MX10202	MX ELASTICATED KNEE SUPPORT WITH STAYS -M	5057881102021	15057881102028
MX10203	MX ELASTICATED KNEE SUPPORT WITH STAYS -L	5057881102038	15057881102035
MX10204	MX ELASTICATED KNEE SUPPORT WITH STAYS -XL	5057881102045	15057881102042
MX10205	MX ELASTICATED KNEE SUPPORT WITH STAYS -XXL	5057881102052	15057881102059
MX10206	MX ELSTICATED KNEE SUPPORT -S	5057881102069	15057881102066
MX10207	MX ELSTICATED KNEE SUPPORT -M	5057881102076	15057881102073
MX10208	MX ELSTICATED KNEE SUPPORT -L	5057881102083	15057881102080
MX10209	MX ELSTICATED KNEE SUPPORT -XL	5057881102090	15057881102097
MX10210	MX ELSTICATED KNEE SUPPORT -XXL	5057881102106	15057881102103
VA10211	VAVIVO ELASTICATED ANKLE SUPPORT-S	5057881102113	15057881102110
VA10221	VAVIVO ELASTICATED ANKLE SUPPORT-M	5057881102212	15057881102219
VA10231	VAVIVO ELASTICATED ANKLE SUPPORT-L	5057881102311	15057881102318
VA10241	VAVIVO ELASTICATED ANKLE SUPPORT-XL	5057881102410	15057881102417
VA10251	VAVIVO ELASTICATED ANKLE SUPPORT - XXL	5057881102519	15057881102516
VA10261	VAVIVO ELASTICATED ANKLE SUPPORT -XXXL	5057881102618	15057881102615
VA12101	VAVIVO Magnetic Neoprene Knee Support - UNI SIZE	5057881121015	15057881121012
VA12201	VAVIVO Magnetic Neoprene Ankle Support - UNI SIZE	5057881122012	15057881122019
VA13001	VAVIVO Neoprene Hinged Knee Support - S	5057881130017	15057881130014
VA13011	VAVIVO Neoprene Hinged Knee Support - M	5057881130116	15057881130113
VA13021	VAVIVO Neoprene Hinged Knee Support - L	5057881130215	15057881130212
VA13031	VAVIVO Neoprene Hinged Knee Support - XL	5057881130314	15057881130311
VA13041	VAVIVO Neoprene Hinged Knee Support - XXL	5057881130413	15057881130410
VA13051	VAVIVO Neoprene Knee Stabilizer - S	5057881130512	15057881130519
VA13061	VAVIVO Neoprene Knee Stabilizer - M	5057881130611	15057881130618
VA13071	VAVIVO Neoprene Knee Stabilizer - L	5057881130710	15057881130717
VA13081	VAVIVO Neoprene Knee Stabilizer - XL	5057881130819	15057881130816
VA13091	VAVIVO Neoprene Knee Stabilizer - XXL	5057881130918	15057881130915
VA13101	VAVIVO Neoprene Knee Support - UNI Size	5057881131014	15057881131011
VA13111	VAVIVO Neoprene Knee Support - O.P-S	5057881131113	15057881131110
VA13121	VAVIVO Neoprene Knee Support - O.P-M	5057881131212	15057881131219

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VA13131	VAVIVO Neoprene Knee Support - O.P-L	5057881131311	15057881131318
VA13141	VAVIVO Neoprene Knee Support - O.P-XL	5057881131410	15057881131417
VA13151	VAVIVO Neoprene Knee Support - O.P-XXL	5057881131519	15057881131516
VA13161	VAVIVO Neoprene Knee Support - O.P-XXXL	5057881131618	15057881131615
VA13171	VAVIVO Neoprene Hinged Knee Support - XXXL	5057881131717	15057881131714
VA13181	VAVIVO Neoprene Knee Stabilizer - XXXL	5057881131816	15057881131813
VA13201	VAVIVO Neoprene Ankle Support - UNI Size	5057881132011	15057881132018
VA13211	VAVIVO Neoprene Ankle Support - S	5057881132110	15057881132117
VA13221	VAVIVO Neoprene Ankle Support - M	5057881132219	15057881132216
VA13231	VAVIVO Neoprene Ankle Support - L	5057881132318	15057881132315
VA13241	VAVIVO Neoprene Ankle Support - XL	5057881132417	15057881132414
VA13251	VAVIVO Neoprene Ankle Support - XXL	5057881132516	15057881132513
VA13261	VAVIVO Neoprene Ankle Support - XXXL	5057881132615	15057881132612
MX71111	STANDARD ELASTICATED KNEE SUPPORT -S	5057881711117	15057881711114
MX71121	STANDARD ELASTICATED KNEE SUPPORT -M	5057881711216	15057881711213
MX71131	STANDARD ELASTICATED KNEE SUPPORT -L	5057881711315	15057881711312
MX71141	STANDARD ELASTICATED KNEE SUPPORT -XL	5057881711414	15057881711411
MX71151	STANDARD ELASTICATED KNEE SUPPORT -XXL	5057881711513	15057881711510
MX71161	STANDARD ELASTICATED KNEE SUPPORT -XXXL	5057881711612	15057881711619
MX71211	STANDARD ELASTICATED ANKLE SUPPORT-S	5057881712114	15057881712111
MX71221	STANDARD ELASTICATED ANKLE SUPPORT-M	5057881712213	15057881712210
MX71231	STANDARD ELASTICATED ANKLE SUPPORT-L	5057881712312	15057881712319
MX71241	STANDARD ELASTICATED ANKLE SUPPORT-XL	5057881712411	15057881712418
MX71251	STANDARD ELASTICATED ANKLE SUPPORT - XXL	5057881712510	15057881712517
MX71261	STANDARD ELASTICATED ANKLE SUPPORT - XXXL	5057881712619	15057881712616
MX72011	PREMIUM ELASTICATED Calf Support-S	5057881720119	15057881720116
MX72021	PREMIUM ELASTICATED Calf Support-M	5057881720218	15057881720215
MX72031	PREMIUM ELASTICATED Calf Support-L	5057881720317	15057881720314
MX72041	PREMIUM ELASTICATED Calf Support-XL	5057881720416	15057881720413
MX72051	PREMIUM ELASTICATED Calf Support-XXL	5057881720515	15057881720512
MX72061	PREMIUM ELASTICATED Calf Support-XXXL	5057881720614	15057881720611
MX72111	PREMIUM ELASTICATED Knee Support-S	5057881721116	15057881721113
MX72121	PREMIUM ELASTICATED Knee Support-M	5057881721215	15057881721212
MX72131	PREMIUM ELASTICATED Knee Support-L	5057881721314	15057881721311
MX72141	PREMIUM ELASTICATED Knee Support-XL	5057881721413	15057881721410
MX72151	PREMIUM ELASTICATED Knee Support-XXL	5057881721512	15057881721519
MX72161	PREMIUM ELASTICATED Knee Support-XXXL	5057881721611	15057881721618
MX72211	PREMIUM ELASTICATED Ankle Support-S	5057881722113	15057881722110
MX72221	PREMIUM ELASTICATED Ankle Support-M	5057881722212	15057881722219
MX72231	PREMIUM ELASTICATED Ankle Support-L	5057881722311	15057881722318

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MX72241	PREMIUM ELASTICATED Ankle Support-XL	5057881722410	15057881722417
MX72251	PREMIUM ELASTICATED Ankle Support-XXL	5057881722519	15057881722516
MX72261	PREMIUM ELASTICATED Ankle Support-XXXL	5057881722618	15057881722615
MX72411	PREMIUM ELASTICATED Thigh Support-S	5057881724117	15057881724114
MX72421	PREMIUM ELASTICATED Thigh Support-M	5057881724216	15057881724213
MX72431	PREMIUM ELASTICATED Thigh Support-L	5057881724315	15057881724312
MX72441	PREMIUM ELASTICATED Thigh Support-XL	5057881724414	15057881724411
MX72451	PREMIUM ELASTICATED Thigh Support-XXL	5057881724513	15057881724510
MX72461	PREMIUM ELASTICATED Thigh Support-XXXL	5057881724612	15057881724619
MX73101	Magnetic Neoprene Knee Support - UNI SIZE	5057881731016	15057881731013
MX73201	Magnetic NEOPRENE Ankle Support-UNI SIZE	5057881732013	15057881732010
MX73991	MAGNETIC NEOPRENE SUPPORTS CDU 22 PCS (4 KNEE, 6 X ANKLE, ELBOW, HAND)	5057881739913	15057881739910
MX74001	Premium Neoprene Hinged Knee Support - XXL	5057881740018	15057881740015
MX74011	Premium Neoprene Hinged Knee Support - S	5057881740117	15057881740114
MX74021	Premium Neoprene Hinged Knee Support - M	5057881740216	15057881740213
MX74031	Premium Neoprene Hinged Knee Support - L	5057881740315	15057881740312
MX74041	Premium Neoprene Hinged Knee Support - XL	5057881740414	15057881740411
MX74051	Premium Neoprene Knee Stabilizer - S	5057881740513	15057881740510
MX74061	Premium Neoprene Knee Stabilizer - M	5057881740612	15057881740619
MX74071	Premium Neoprene Knee Stabilizer - L	5057881740711	15057881740718
MX74081	Premium Neoprene Knee Stabilizer - XL	5057881740810	15057881740817
MX74091	Premium NEOPRENE Knee Stabilizer-XXL	5057881740919	15057881740916
MX74101	Premium Universal Knee Support - UNI S/M/L	5057881741015	15057881741012
MX74111	Premium Neoprene Knee Support - Open Patella -S	5057881741114	15057881741111
MX74121	Premium Neoprene Knee Support - Open Patella- M	5057881741213	15057881741210
MX74131	Premium Neoprene Knee Support - Open Patella-L	5057881741312	15057881741319
MX74141	Premium Neoprene Knee Support - Open Patella-XL	5057881741411	15057881741418
MX74151	Premium Neoprene Knee Support - Open Patella-XXL	5057881741510	15057881741517
MX74161	Premium Neoprene Knee Support - Open Patella -XXXL	5057881741619	15057881741616
MX74171	Premium UNIVERSAL Knee Support-UNI+ L/XL/XXL	5057881741718	15057881741715
MX74181	Premium Neoprene Hinged Knee Support - XXXL	5057881741817	15057881741814
MX74191	Premium Neoprene Knee Stabilizer - XXXL	5057881741916	15057881741913
MX74201	Premium Universal Ankle Support - UNI S/M/L	5057881742012	15057881742019
MX74211	Premium Neoprene Ankle Support - S	5057881742111	15057881742118
MX74221	Premium Neoprene Ankle Support - M	5057881742210	15057881742217
MX74231	Premium Neoprene Ankle Support - L	5057881742319	15057881742316
MX74241	Premium Neoprene Ankle Support - XL	5057881742418	15057881742415
MX74251	Premium Neoprene Ankle Support - XXL	5057881742517	15057881742514
MX74261	Premium Neoprene Ankle Support - XXXL	5057881742616	15057881742613

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MX74271	Premium Universal Ankle Support - UNI+ L/XL/XXL	5057881742715	15057881742712
MX75313	Orthopaedic Support Ankle	5057881753131	15057881753138
MX75511	PREMIUM ELASTICATED WRAP GREY BLACK - KNEE	5057881755111	15057881755118
MX75521	PREMIUM ELASTICATED WRAP GREY BLACK- ANKLE	5057881755210	15057881755217
MX75611	PREMIUM ELASTICATED WRAP CAMO GREEN - KNEE	5057881756118	15057881756115
MX75621	PREMIUM ELASTICATED WRAP CAMO GREEN - ANKLE	5057881756217	15057881756214
MX77051	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE RIGHT S/M	5057881770510	15057881770517
MX77056	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE LEFT S/M	5057881770565	15057881770562
MX77057	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE LEFT M/L	5057881770572	15057881770579
MX77058	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE RIGHT M/L	5057881770589	15057881770586
OE80022	CEROX ANKLE ELASTICATED WRAP (172030)	8002945750653	15057881800221
OE80023	CEROX KNEE ELASTICATED WRAP (172031)	8002945750660	15057881800238

Version Control:

Change	Date	Version number
Creation date	4 th June 2021	1.0
Use new format	7 th July 2021	1.1
Add BASIC UDI-DI	8 th July 2021	1.2
Add Eudamed Manufacturer Number	28 th September 2021.	1.3