





## 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	505788110111BR	
Product trade name	MX SUPPORTS FAMILY – EMDN GROUP 3	
Product Code Number	See Appendix A of this document	
EMDN Code	Y061212	
Intended purpose	An external orthosis designed to support the ankle, knee, thigh	
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	2021-10-29
Name of issuing officer	Mr J. J. Viljoen
Signature	
Designation	Senior Regulatory Officer
Signed on behalf of	Medinox London Limited
Company stamp	 <p><b>medinox<sup>®</sup></b> Medinox London Ltd Solar House, 282 Chase Road London N14 6NZ www.medinox.co.uk Company Number 11149212</p>

Appendix A

Product listings:

CODE	DESCRIPTION	EMDN	BARCODE	OUTER CASE BARCODE	BASIC UDI
VA10111	VAVIVO ELASTICATED KNEE SUPPORT -S	3	5057881101116	15057881101113	505788110111BR
VA10121	VAVIVO ELASTICATED KNEE SUPPORT -M	3	5057881101215	15057881101212	505788110111BR
VA10131	VAVIVO ELASTICATED KNEE SUPPORT -L	3	5057881101314	15057881101311	505788110111BR
VA10141	VAVIVO ELASTICATED KNEE SUPPORT -XL	3	5057881101413	15057881101410	505788110111BR
VA10151	VAVIVO ELASTICATED KNEE SUPPORT -XXL	3	5057881101512	15057881101519	505788110111BR
VA10161	VAVIVO ELASTICATED KNEE SUPPORT -XXXL	3	5057881101611	15057881101618	505788110111BR
MX10201	MX ELASTICATED KNEE SUPPORT WITH STAYS -S	3	5057881102014	15057881102011	505788110111BR
MX10202	MX ELASTICATED KNEE SUPPORT WITH STAYS -M	3	5057881102021	15057881102028	505788110111BR
MX10203	MX ELASTICATED KNEE SUPPORT WITH STAYS -L	3	5057881102038	15057881102035	505788110111BR
MX10204	MX ELASTICATED KNEE SUPPORT WITH STAYS -XL	3	5057881102045	15057881102042	505788110111BR
MX10205	MX ELASTICATED KNEE SUPPORT WITH STAYS -XXL	3	5057881102052	15057881102059	505788110111BR
MX10206	MX ELSTICATED KNEE SUPPORT -S	3	5057881102069	15057881102066	505788110111BR
MX10207	MX ELSTICATED KNEE SUPPORT -M	3	5057881102076	15057881102073	505788110111BR
MX10208	MX ELSTICATED KNEE SUPPORT -L	3	5057881102083	15057881102080	505788110111BR
MX10209	MX ELSTICATED KNEE SUPPORT -XL	3	5057881102090	15057881102097	505788110111BR
MX10210	MX ELSTICATED KNEE SUPPORT -XXL	3	5057881102106	15057881102103	505788110111BR
VA10211	VAVIVO ELASTICATED ANKLE SUPPORT-S	3	5057881102113	15057881102110	505788110211BW
VA10221	VAVIVO ELASTICATED ANKLE SUPPORT-M	3	5057881102212	15057881102219	505788110211BW
VA10231	VAVIVO ELASTICATED ANKLE SUPPORT-L	3	5057881102311	15057881102318	505788110211BW
VA10241	VAVIVO ELASTICATED ANKLE SUPPORT-XL	3	5057881102410	15057881102417	505788110211BW
VA10251	VAVIVO ELASTICATED ANKLE SUPPORT - XXL	3	5057881102519	15057881102516	505788110211BW
VA10261	VAVIVO ELASTICATED ANKLE SUPPORT - XXXL	3	5057881102618	15057881102615	505788110211BW
VA12101	VAVIVO Magnetic Neoprene Knee Support - UNI SIZE	3	5057881121015	15057881121012	505788110111BR
VA12201	VAVIVO Magnetic Neoprene Ankle Support - UNI SIZE	3	5057881122012	15057881122019	505788110211BW
VA13001	VAVIVO Neoprene Hinged Knee Support - S	3	5057881130017	15057881130014	505788110111BR
VA13011	VAVIVO Neoprene Hinged Knee Support - M	3	5057881130116	15057881130113	505788110111BR
VA13021	VAVIVO Neoprene Hinged Knee Support - L	3	5057881130215	15057881130212	505788110111BR
VA13031	VAVIVO Neoprene Hinged Knee Support - XL	3	5057881130314	15057881130311	505788110111BR

CODE	DESCRIPTION	EMDN	BARCODE	OUTER CASE BARCODE	BASIC UDI
VA13041	VAVIVO Neoprene Hinged Knee Support - XXL	3	5057881130413	15057881130410	505788110111BR
VA13051	VAVIVO Neoprene Knee Stabilizer - S	3	5057881130512	15057881130519	505788110111BR
VA13061	VAVIVO Neoprene Knee Stabilizer - M	3	5057881130611	15057881130618	505788110111BR
VA13071	VAVIVO Neoprene Knee Stabilizer - L	3	5057881130710	15057881130717	505788110111BR
VA13081	VAVIVO Neoprene Knee Stabilizer - XL	3	5057881130819	15057881130816	505788110111BR
VA13091	VAVIVO Neoprene Knee Stabilizer - XXL	3	5057881130918	15057881130915	505788110111BR
VA13101	VAVIVO Neoprene Knee Support - UNI Size	3	5057881131014	15057881131011	505788110111BR
VA13111	VAVIVO Neoprene Knee Support - O.P-S	3	5057881131113	15057881131110	505788110111BR
VA13121	VAVIVO Neoprene Knee Support - O.P-M	3	5057881131212	15057881131219	505788110111BR
VA13131	VAVIVO Neoprene Knee Support - O.P-L	3	5057881131311	15057881131318	505788110111BR
VA13141	VAVIVO Neoprene Knee Support - O.P-XL	3	5057881131410	15057881131417	505788110111BR
VA13151	VAVIVO Neoprene Knee Support - O.P-XXL	3	5057881131519	15057881131516	505788110111BR
VA13161	VAVIVO Neoprene Knee Support - O.P-XXXL	3	5057881131618	15057881131615	505788110111BR
VA13171	VAVIVO Neoprene Hinged Knee Support - XXXL	3	5057881131717	15057881131714	505788110111BR
VA13181	VAVIVO Neoprene Knee Stabilizer - XXXL	3	5057881131816	15057881131813	505788110111BR
VA13201	VAVIVO Neoprene Ankle Support - UNI Size	3	5057881132011	15057881132018	505788110211BW
VA13211	VAVIVO Neoprene Ankle Support - S	3	5057881132110	15057881132117	505788110211BW
VA13221	VAVIVO Neoprene Ankle Support - M	3	5057881132219	15057881132216	505788110211BW
VA13231	VAVIVO Neoprene Ankle Support - L	3	5057881132318	15057881132315	505788110211BW
VA13241	VAVIVO Neoprene Ankle Support - XL	3	5057881132417	15057881132414	505788110211BW
VA13251	VAVIVO Neoprene Ankle Support - XXL	3	5057881132516	15057881132513	505788110211BW
VA13261	VAVIVO Neoprene Ankle Support - XXXL	3	5057881132615	15057881132612	505788110211BW
MX71111	STANDARD ELASTICATED KNEE SUPPORT -S	3	5057881711117	15057881711114	505788110111BR
MX71121	STANDARD ELASTICATED KNEE SUPPORT -M	3	5057881711216	15057881711213	505788110111BR
MX71131	STANDARD ELASTICATED KNEE SUPPORT -L	3	5057881711315	15057881711312	505788110111BR
MX71141	STANDARD ELASTICATED KNEE SUPPORT - XL	3	5057881711414	15057881711411	505788110111BR
MX71151	STANDARD ELASTICATED KNEE SUPPORT - XXL	3	5057881711513	15057881711510	505788110111BR
MX71161	STANDARD ELASTICATED KNEE SUPPORT - XXXL	3	5057881711612	15057881711619	505788110111BR
MX71211	STANDARD ELASTICATED ANKLE SUPPORT-S	3	5057881712114	15057881712111	505788110211BW
MX71221	STANDARD ELASTICATED ANKLE SUPPORT-M	3	5057881712213	15057881712210	505788110211BW
MX71231	STANDARD ELASTICATED ANKLE SUPPORT-L	3	5057881712312	15057881712319	505788110211BW
MX71241	STANDARD ELASTICATED ANKLE SUPPORT-XL	3	5057881712411	15057881712418	505788110211BW
MX71251	STANDARD ELASTICATED ANKLE SUPPORT - XXL	3	5057881712510	15057881712517	505788110211BW

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MX71261	STANDARD ELASTICATED ANKLE SUPPORT - XXXL	3	5057881712619	15057881712616	505788110211BW
MX72011	PREMIUM ELASTICATED Calf Support-S	3	5057881720119	15057881720116	505788110111BR
MX72021	PREMIUM ELASTICATED Calf Support-M	3	5057881720218	15057881720215	505788110111BR
MX72031	PREMIUM ELASTICATED Calf Support-L	3	5057881720317	15057881720314	505788110111BR
MX72041	PREMIUM ELASTICATED Calf Support-XL	3	5057881720416	15057881720413	505788110111BR
MX72051	PREMIUM ELASTICATED Calf Support-XXL	3	5057881720515	15057881720512	505788110111BR
MX72061	PREMIUM ELASTICATED Calf Support-XXXL	3	5057881720614	15057881720611	505788110111BR
MX72111	PREMIUM ELASTICATED Knee Support-S	3	5057881721116	15057881721113	505788110111BR
MX72121	PREMIUM ELASTICATED Knee Support-M	3	5057881721215	15057881721212	505788110111BR
MX72121	PREMIUM ELASTICATED Knee Support-Medium 12 pcs inner box - @@@	3	5057881721222	15057881721229	505788110111BR
MX72131	PREMIUM ELASTICATED Knee Support-L	3	5057881721314	15057881721311	505788110111BR
MX72131	PREMIUM ELASTICATED Knee Support-LRGE 12 PIECES INNER BOX - @@@	3	5057881721321	15057881721328	505788110111BR
MX72141	PREMIUM ELASTICATED Knee Support-XL	3	5057881721413	15057881721410	505788110111BR
MX72151	PREMIUM ELASTICATED Knee Support-XXL	3	5057881721512	15057881721519	505788110111BR
MX72161	PREMIUM ELASTICATED Knee Support-XXXL	3	5057881721611	15057881721618	505788110111BR
SY72162	Stabilizator kolana MX Line (Ortopedio by Synoptis) S	3	5057881721628	15057881721625	505788110111BR
SY72163	Stabilizator kolana MX Line (Ortopedio by Synoptis) M	3	5057881721635	15057881721632	505788110111BR
SY72164	Stabilizator kolana MX Line (Ortopedio by Synoptis) L	3	5057881721642	15057881721649	505788110111BR
SY72165	Stabilizator kolana MX Line (Ortopedio by Synoptis) XL	3	5057881721659	15057881721656	505788110111BR
SY72166	Stabilizator kolana MX Line (Ortopedio by Synoptis) XXL	3	5057881721666	15057881721663	505788110111BR
SY72167	Stabilizator kolana MX Line (Ortopedio by Synoptis) XXXL	3	5057881721673	15057881721670	505788110111BR
MX72211	PREMIUM ELASTICATED Ankle Support-S	3	5057881722113	15057881722110	505788110211BW
MX72221	PREMIUM ELASTICATED Ankle Support-M	3	5057881722212	15057881722219	505788110211BW
MX72221	PREMIUM ELASTICATED Ankle Support-Medium 12 pcs inner box - @@@	3	5057881722229	15057881722226	505788110211BW
MX72231	PREMIUM ELASTICATED Ankle Support-L	3	5057881722311	15057881722318	505788110211BW
MX72231	PREMIUM ELASTICATED Ankle Support-Large 12 pcs inner box - @@@	3	5057881722328	15057881722325	505788110211BW
MX72241	PREMIUM ELASTICATED Ankle Support-XL	3	5057881722410	15057881722417	505788110211BW
MX72251	PREMIUM ELASTICATED Ankle Support-XXL	3	5057881722519	15057881722516	505788110211BW
MX72261	PREMIUM ELASTICATED Ankle Support-XXXL	3	5057881722618	15057881722615	505788110211BW
MX72411	PREMIUM ELASTICATED Thigh Support-S	3	5057881724117	15057881724114	505788110111BR

CODE	DESCRIPTION	EMDN	BARCODE	OUTER CASE BARCODE	BASIC UDI
MX72421	PREMIUM ELASTICATED Thigh Support-M	3	5057881724216	15057881724213	505788110111BR
MX72431	PREMIUM ELASTICATED Thigh Support-L	3	5057881724315	15057881724312	505788110111BR
MX72441	PREMIUM ELASTICATED Thigh Support-XL	3	5057881724414	15057881724411	505788110111BR
MX72451	PREMIUM ELASTICATED Thigh Support-XXL	3	5057881724513	15057881724510	505788110111BR
MX72461	PREMIUM ELASTICATED Thigh Support-XXXL	3	5057881724612	15057881724619	505788110111BR
SY72662	PREMIUM ELASTICATED Ankle Support-S (Only for Synoptis)	3	5057881726623	15057881726620	505788110211BW
SY72663	PREMIUM ELASTICATED Ankle Support-M (Only for Synoptis)	3	5057881726630	15057881726637	505788110211BW
SY72664	PREMIUM ELASTICATED Ankle Support-L (Only for Synoptis)	3	5057881726647	15057881726644	505788110211BW
SY72665	PREMIUM ELASTICATED Ankle Support-XL (Only for Synoptis)	3	5057881726654	15057881726651	505788110211BW
SY72666	PREMIUM ELASTICATED Ankle Support-XXL (Only for Synoptis)	3	5057881726661	15057881726668	505788110211BW
SY72667	PREMIUM ELASTICATED Ankle Support-XXXL (Only for Synoptis)	3	5057881726678	15057881726675	505788110211BW
MX73101	Magnetic Neoprene Knee Support - UNI SIZE	3	5057881731016	15057881731013	505788110111BR
MX73201	Magnetic NEOPRENE Ankle Support-UNI SIZE	3	5057881732013	15057881732010	505788110211BW
MX73991	MAGNETIC NEOPRENE SUPPORTS CDU 22 PCS (4 KNEE, 6 X ANKLE, ELBOW, HAND)	3	5057881739913	15057881739910	505788110111BR
MX74001	Premium Neoprene Hinged Knee Support - XXL	3	5057881740018	15057881740015	505788110111BR
MX74011	Premium Neoprene Hinged Knee Support - S	3	5057881740117	15057881740114	505788110111BR
MX74021	Premium Neoprene Hinged Knee Support - M	3	5057881740216	15057881740213	505788110111BR
MX74031	Premium Neoprene Hinged Knee Support - L	3	5057881740315	15057881740312	505788110111BR
MX74041	Premium Neoprene Hinged Knee Support - XL	3	5057881740414	15057881740411	505788110111BR
MX74051	Premium Neoprene Knee Stabilizer - S	3	5057881740513	15057881740510	505788110111BR
MX74061	Premium Neoprene Knee Stabilizer - M	3	5057881740612	15057881740619	505788110111BR
MX74071	Premium Neoprene Knee Stabilizer - L	3	5057881740711	15057881740718	505788110111BR
MX74081	Premium Neoprene Knee Stabilizer - XL	3	5057881740810	15057881740817	505788110111BR
MX74091	Premium NEOPRENE Knee Stabilizer-XXL	3	5057881740919	15057881740916	505788110111BR
MX74101	Premium Universal Knee Support - UNI S/M/L	3	5057881741015	15057881741012	505788110111BR
MX74111	Premium Neoprene Knee Support - Open Patella -S	3	5057881741114	15057881741111	505788110111BR



CODE	DESCRIPTION	EMDN	BARCODE	OUTER CASE BARCODE	BASIC UDI
MX74121	Premium Neoprene Knee Support - Open Patella- M	3	5057881741213	15057881741210	505788110111BR
MX74131	Premium Neoprene Knee Support - Open Patella-L	3	5057881741312	15057881741319	505788110111BR
MX74141	Premium Neoprene Knee Support - Open Patella-XL	3	5057881741411	15057881741418	505788110111BR
MX74151	Premium Neoprene Knee Support - Open Patella-XXL	3	5057881741510	15057881741517	505788110111BR
MX74161	Premium Neoprene Knee Support - Open Patella -XXXL	3	5057881741619	15057881741616	505788110111BR
MX74171	Premium UNIVERSAL Knee Support-UNI+ L/XL/XXL	3	5057881741718	15057881741715	505788110111BR
MX74181	Premium Neoprene Hinged Knee Support - XXXL	3	5057881741817	15057881741814	505788110111BR
MX74191	Premium Neoprene Knee Stabilizer - XXXL	3	5057881741916	15057881741913	505788110111BR
MX74201	Premium Universal Ankle Support - UNI S/M/L	3	5057881742012	15057881742019	505788110211BW
MX74211	Premium Neoprene Ankle Support - S	3	5057881742111	15057881742118	505788110211BW
MX74221	Premium Neoprene Ankle Support - M	3	5057881742210	15057881742217	505788110211BW
MX74231	Premium Neoprene Ankle Support - L	3	5057881742319	15057881742316	505788110211BW
MX74241	Premium Neoprene Ankle Support - XL	3	5057881742418	15057881742415	505788110211BW
MX74251	Premium Neoprene Ankle Support - XXL	3	5057881742517	15057881742514	505788110211BW
MX74261	Premium Neoprene Ankle Support - XXXL	3	5057881742616	15057881742613	505788110211BW
MX74271	Premium Universal Ankle Support - UNI+ L/XL/XXL	3	5057881742715	15057881742712	505788110211BW
MX75313	Orthopaedic Support Ankle	3	5057881753131	15057881753138	505788110211BW
MX75511	PREMIUM ELASTICATED WRAP GREY BLACK - KNEE	3	5057881755111	15057881755118	505788110111BR
MX75521	PREMIUM ELASTICATED WRAP GREY BLACK- ANKLE	3	5057881755210	15057881755217	505788110211BW
MX75611	PREMIUM ELASTICATED WRAP CAMO GREEN - KNEE	3	5057881756118	15057881756115	505788110111BR
MX75621	PREMIUM ELASTICATED WRAP CAMO GREEN - ANKLE	3	5057881756217	15057881756214	505788110211BW
MX76122	MX SMALL ELASTICATED WRAP 40 X 7.5CM	3	5057881761228	15057881761225	505788110111BR
MX76123	MX MEDIUM ELASTICATED WRAP 80 X 7.5CM	3	5057881761235	15057881761232	505788110111BR
MX76124	MX LARGE ELASTICATED WRAP 120 X 7.5CM	3	5057881761242	15057881761249	505788110111BR
MX77051	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE RIGHT S/M	3	5057881770510	15057881770517	505788110211BW
MX77056	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE LEFT S/M	3	5057881770565	15057881770562	505788110211BW

CODE	DESCRIPTION	EMDN	BARCODE	OUTER CASE BARCODE	BASIC UDI
MX77057	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE LEFT M/L	3	5057881770572	15057881770579	505788110211BW
MX77058	MX ORTHOPAEDIC ADJUSTABLE ANKLE BRACE RIGHT M/L	3	5057881770589	15057881770586	505788110211BW
OE80022	CEROX ANKLE ELASTICATED WRAP (172030)	3	5057881800224	15057881800221	505788110211BW
OE80023	CEROX KNEE ELASTICATED WRAP (172031)	3	5057881800231	15057881800238	505788110111BR

Version control:

Change	Date	Version number
Creation date	4 <sup>th</sup> June 2021	1.0
Use new format	7 <sup>th</sup> July 2021	1.1
Add BASIC UDI-DI	8 <sup>th</sup> July 2021	1.2
Add manufacturer SRN allocated by EUDAMED	29 <sup>th</sup> October 2021	1.3
Split Elbow DOC from wrist and hand. New GMDN codes allocated by the GMDN agency.	3 <sup>rd</sup> February 2022	1.4
Add EMDN code and remove GMDN code	10 <sup>th</sup> February 2022	1.5
Regroup EMDN Codes	10 August 2022	1.51