





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	505788110611CJ	
Product trade name	MX SUPPORTS FAMILY – EMDN GROUP 4 WAISTE AND BACK	
Product Code Number	See Appendix A of this document	
EMDN Code	Y060308	
Intended purpose	An external orthosis designed to support the waist and back. (LUMBOSACRAL SPINE ORTHOSES)	
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>medinox[®] 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
VA10611	VAVIVO ELASTICATED WAIST BELT - S	4	5057881106111	15057881106118	505788110611CJ
VA10621	VAVIVO ELASTICATED WAIST BELT - M	4	5057881106210	15057881106217	505788110611CJ
VA10631	VAVIVO ELASTICATED WAIST BELT - L	4	5057881106319	15057881106316	505788110611CJ
VA10641	VAVIVO ELASTICATED WAIST BELT - XL	4	5057881106418	15057881106415	505788110611CJ
VA10651	VAVIVO ELASTICATED WAIST BELT - XXL	4	5057881106517	15057881106514	505788110611CJ
VA10661	VAVIVO ELASTICATED WAIST BELT - XXXL	4	5057881106616	15057881106613	505788110611CJ
VA10701	VAVIVO ELASTICATED BACK SUPPORT W/STAYS -XSMALL	4	5057881107019	15057881107016	505788110611CJ
VA10711	VAVIVO ELASTICATED BACK SUPPORT W/STAYS -SMALL	4	5057881107118	15057881107115	505788110611CJ
VA10721	VAVIVO ELASTICATED BACK SUPPORT W/STAYS - MEDIUM	4	5057881107217	15057881107214	505788110611CJ
VA10731	VAVIVO ELASTICATED BACK SUPPORT W/STAYS - LARGE	4	5057881107316	15057881107313	505788110611CJ
VA10741	VAVIVO ELASTICATED BACK SUPPORT W/STAYS - X-LARGE	4	5057881107415	15057881107412	505788110611CJ
VA10751	VAVIVO ELASTICATED BACK SUPPORT W/STAYS - XX-LARGE	4	5057881107514	15057881107511	505788110611CJ
VA10771	VAVIVO ELASTICATED BACK SUPPORT W/STAYS - UNI	4	5057881107712	15057881107719	505788110611CJ
VA12701	VAVIVO Magnetic Neoprene Back Support - UNI SIZE	4	5057881127017	15057881127014	505788110611CJ
VA13711	VAVIVO Neoprene Back Support with S - S	4	5057881137115	15057881137112	505788110611CJ
VA13721	VAVIVO Neoprene Back Support with S - M	4	5057881137214	15057881137211	505788110611CJ
VA13731	VAVIVO Neoprene Back Support with S - L	4	5057881137313	15057881137310	505788110611CJ
VA13741	VAVIVO Neoprene Back Support with S - XL	4	5057881137412	15057881137419	505788110611CJ
VA13751	VAVIVO Neoprene Back Support with S - XXL	4	5057881137511	15057881137518	505788110611CJ
VA13761	VAVIVO Neoprene Back Support with S - XXXL	4	5057881137610	15057881137617	505788110611CJ
MX71611	STANDARD ELASTICATED WAIST BELT - S	4	5057881716112	15057881716119	505788110611CJ
MX71621	STANDARD ELASTICATED WAIST BELT - M	4	5057881716211	15057881716218	505788110611CJ
MX71631	STANDARD ELASTICATED WAIST BELT - L	4	5057881716310	15057881716317	505788110611CJ

CODE	DESCRIPTION	EMDN	BARCODE	OUTER CASE BARCODE	BASIC UDI
MX71641	STANDARD ELASTICATED WAIST BELT - XL	4	5057881716419	15057881716416	505788110611CJ
MX71651	STANDARD ELASTICATED WAIST BELT - XXL	4	5057881716518	15057881716515	505788110611CJ
MX71661	STANDARD ELASTICATED WAIST BELT - XXXL	4	5057881716617	15057881716614	505788110611CJ
MX71681	STANDARD ELASTICATED Waist Support Belt-UNI	4	5057881716815	15057881716812	505788110611CJ
MX71711	STANDARD ELASTICATED BACK SUPPORT W/STAYS -SMALL	4	5057881717119	15057881717116	505788110611CJ
MX71721	STANDARD ELASTICATED Back Support W/STAYS-M	4	5057881717218	15057881717215	505788110611CJ
MX71731	STANDARD ELASTICATED Back Support W/STAYS-L	4	5057881717317	15057881717314	505788110611CJ
MX71741	STANDARD ELASTICATED BACK SUPPORT W/STAYS - X-LARGE	4	5057881717416	15057881717413	505788110611CJ
MX71751	STANDARD ELASTICATED BACK SUPPORT W/STAYS - XXLARGE	4	5057881717515	15057881717512	505788110611CJ
MX71781	STANDARD ELASTICATED Back Support W/STAYS-UNI	4	5057881717812	15057881717819	505788110611CJ
MX72611	PREMIUM ELASTICATED Waist Support Belt UNI S/M/L	4	5057881726111	15057881726118	505788110611CJ
MX72612	PREMIUM ELASTICATED Waist Support Belt UNI+ L/XL/XXL	4	5057881726128	15057881726125	505788110611CJ
MX72711	PREMIUM ELASTICATED Back Support UNI S/M/L	4	5057881727118	15057881727115	505788110611CJ
MX72721	PREMIUM ELASTICATED Back Support UNI+ L-XXL	4	5057881727217	15057881727214	505788110611CJ
SY72722	Pas stabilizujący odcinek lędźwiowy MX Line (Ortopedio by Synoptis) S/M/L	4	5057881727224	15057881727221	505788110611CJ
SY72723	Pas stabilizujący odcinek lędźwiowy MX Line (Ortopedio by Synoptis) L/XL/XXL	4	5057881727231	15057881727238	505788110611CJ
SY72724	Pas usztywniający plecy MX Line (Ortopedio by Synoptis) S/M/L	4	5057881727248	15057881727245	505788110611CJ
SY72725	Pas usztywniający plecy MX Line (Ortopedio by Synoptis) L/XXL/XXXL	4	5057881727255	15057881727252	505788110611CJ
MX73701	Magnetic Neoprene Back Support - UNI SIZE	4	5057881737018	15057881737015	505788110611CJ
MX74711	Premium NEOPRENE Back Support UNI S/M/L	4	5057881747116	15057881747113	505788110611CJ
MX74721	Premium NEOPRENE Back Support UNI+ XL-XXXL	4	5057881747215	15057881747212	505788110611CJ
MX77059	MX MATERNITY BELT BEIGE UNI WITH VELCRO	4	5057881770596	15057881770593	505788110611CJ

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 manufacturer SRN allocated by EUDAMED	29 th October 2021	1.3
Split Elbow DOC from wrist and hand. New GMDN codes allocated by the GMDN agency.	3 rd February 2022	1.4
Add EMDN code and remove GMDN code	10 th February 2022	1.5
Regroup EMDN Codes	10 August 2022	1.51