





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	505788112901DC	
Product trade name	MX SUPPORTS FAMILY GROUP 1	
Product Code Number	See Appendix A of this document	
EMDN Code	Y060312	
Intended purpose	An external orthosis designed to support the cervical spine (neck). This is a reusable device.	
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
VA12901	VAVIVO Magnetic Neoprene Neck Wrap - UNI SIZE	1	5057881129011	15057881129018	505788112901DC
VA14111	VAVIVO Soft Collar (White) - SMALL	1	5057881141112	15057881141119	505788112901DC
VA14121	VAVIVO Soft Collar (White) - MEDIUM	1	5057881141211	15057881141218	505788112901DC
VA14131	VAVIVO Soft Collar (White) - LARGE	1	5057881141310	15057881141317	505788112901DC
VA14141	VAVIVO Soft Collar (White) - X LARGE	1	5057881141419	15057881141416	505788112901DC
VA14151	VAVIVO Soft Collar (White) - XX LARGE	1	5057881141518	15057881141515	505788112901DC
VA14161	VAVIVO Soft Collar (White) - XXX LARGE	1	5057881141617	15057881141614	505788112901DC
VA14211	VAVIVO Soft Collar (Navy) - SMALL	1	5057881142119	15057881142116	505788112901DC
VA14221	VAVIVO Soft Collar (Navy) - MEDIUM	1	5057881142218	15057881142215	505788112901DC
VA14231	VAVIVO Soft Collar (Navy) - LARGE	1	5057881142317	15057881142314	505788112901DC
VA14241	VAVIVO Soft Collar (Navy) - X LARGE	1	5057881142416	15057881142413	505788112901DC
VA14251	VAVIVO Soft Collar (Navy) - XX LARGE	1	5057881142515	15057881142512	505788112901DC
MX73901	Magnetic Neoprene Neck Wrap - UNI SIZE	1	5057881739012	15057881739019	505788112901DC
MX75111	Orthopaedic Support Soft Collar (White) - SMALL	1	5057881751113	15057881751110	505788112901DC
MX75121	Orthopaedic Support Soft Collar (White) - MEDIUM	1	5057881751212	15057881751219	505788112901DC
MX75131	Orthopaedic Support Soft Collar (White) - LARGE	1	5057881751311	15057881751318	505788112901DC
MX75141	Orthopaedic Support Soft Collar (White) - X LARGE	1	5057881751410	15057881751417	505788112901DC
MX75151	Orthopaedic Support Soft Collar (White) - XX LARGE	1	5057881751519	15057881751516	505788112901DC
MX75161	Orthopaedic Support Soft Collar (White) - XXX LARGE	1	5057881751618	15057881751615	505788112901DC
MX75211	Orthopaedic Support Soft Collar (Navy) - SMALL	1	5057881752110	15057881752117	505788112901DC
MX75221	Orthopaedic Support Soft Collar (Navy) - MEDIUM	1	5057881752219	15057881752216	505788112901DC
MX75231	Orthopaedic Support Soft Collar (Navy) - LARGE	1	5057881752318	15057881752315	505788112901DC

CODE	DESCRIPTION	EMDN	BARCODE	OUTER CASE BARCODE	BASIC UDI
MX75241	Orthopaedic Support Soft Collar (Navy) - X LARGE	1	5057881752417	15057881752414	505788112901DC
MX75251	Orthopaedic Support Soft Collar (Navy) - XX LARGE	1	5057881752516	15057881752513	505788112901DC

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 DOC's New GMDN codes allocated by the GMDN agency.	3 rd February 2022	1.4
Replace the GMDN Code with EMDN Code	10 th February 2022	1.5
Regroup EMDN codes	10 August 2022	1.51