





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	
Product trade name	VITAPLUS CAST PROTECTOR FAMILY	
Product Code Number	See Appendix A of this document	
GMDN Code	33535	
Intended purpose	To protect a bandage or cast from water damage whilst showering or bathing.	
Risk Class according to Annex VIII	Class I rule 1.	
Statement that this device is 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	2021-06-04
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
VP65401	VITAPLUS CAST PROTECTOR ADULT LOWER ARM	5057881654018	15057881654015
VP65411	VITAPLUS CAST PROTECTOR ADULT LOWER ARM - WIDE	5057881654117	15057881654114
VP65421	VITAPLUS CAST PROTECTOR ADULT FULL ARM	5057881654216	15057881654213
VP65451	VITAPLUS CAST PROTECTOR ADULT HAND	5057881654513	15057881654510
VP65471	VITAPLUS CAST PROTECTOR ADULT FOOT	5057881654711	15057881654718
VP65481	VITAPLUS CAST PROTECTOR ADULT LOWER LEG	5057881654810	15057881654817
VP65491	VITAPLUS CAST PROTECTOR ADULT FULL LEG	5057881654919	15057881654916
VP65501	VITAPLUS CAST PROTECTOR CHILD LOWER ARM	5057881655015	15057881655012
VP65511	VITAPLUS CAST PROTECTOR CHILD FULL ARM	5057881655114	15057881655111
VP65541	VITAPLUS CAST PROTECTOR CHILD LOWER LEG	5057881655411	15057881655418
VP65551	VITAPLUS CAST PROTECTOR CHILD FULL LEG	5057881655510	15057881655517