

Declaration of Conformity

for SEERS MEDICAL Clinical Range

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

General Product Name:	Clinical Range
Legal Manufacturer: (Name on Label)	SEERS MEDICAL Ltd. Kenton Road, Debenham, Suffolk IP14 6LA, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Clinical couches for patient Examination and Minor treatment procedures
MDR Classification:	Class I Rule I
Notified Body:	Not Applicable
EC Certificate:	Self-certification
Basic UDI:	05056123CLINIC6L
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN	MT-AR-000000234
Medical Device Directive Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

Name: Simon Rees **Position:** CEO & Founder

Signature:  **Date:** 2024-04-05 **Place:** Debenham, UK

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 this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

SEERS MEDICAL LTD

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Effective date: 2024-04-05

Issue 2

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
MDR 2017/745	Medical Device Regulation MDR 2017/745.
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
RoHS 2011/65/EN	European directive - Restriction of Hazardous Substances
Reach EC 1907/2006	European directive - Registration, Evaluation, Authorization and Restriction of Chemical

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code	UDI DI
SM2550	Medicare Standard 2 section couches (240KG Safe Working load) - hydraulic with manual backrest (Retractable Wheel Design)	42486	05056123800053
SM2560	Medicare Standard 2 section couches (240kg Safe working load) -electric with manual backrest (Retractable Wheel Design)	31362	05056123800206
SM2570	Medicare standard 2 section couches (240KG Safe working load) - Electric with electric back rest (Retractable Wheel Design)	31362	05056123800503
MG2670	Innovation standard 2 section couch (250KG Safe working load) - Electric height with electric backrest (Large Mobile Wheel Design)	31362	05056123801708
MG2470	Innovation standard 2 section couch(250KG Safe Working Load) - Electric height with electric backrest (Large Independent Brake Castor)	31362	05056123801555
MG2675	Innovation Deluxe 2section Couches (250kg Safe working Load) – Electric height back rest , 2-waytilt and CPR facility -Paper roll holder and head cushion (large mobile wheel design)	31362	05056123802309
MG2475	Innovation Deluxe 2section Couches (250kg Safe working Load) – Electric height back rest , 2-waytilt and CPR facility -Paper roll holder and head cushion (Large Independent Brake Castor)	31362	05056123802156
SM2450	Medicare Mobile Treatment Couches (240Kg safe Working Load) 2 section Hydraulic , with manual backrest and support rails -PRH (LIBC)	42486	05056123802750

SEERS MEDICAL LTD

Document Number: SM-000536-TC



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Effective date: 2024-04-05

Issue 2

SM2460	Medicare Mobile Treatment Couches (240Kg safe Working Load) 2 section electric , with manual backrest and support rails -PRH (LIBC)	31362	05056123841025
SM2470	Medicare Mobile Treatment Couches (240Kg safe Working Load) 2 section electric , with electric backrest and support rails -PRH (LIBC)	31362	05056123841032
SM2650	Medicare Mobile Treatment Couches (240Kg safe Working Load) 2 section Hydraulic , with manual backrest and support rails -PRH (LMWD)	42486	05056123802903
SM2660	Medicare Mobile Treatment Couches (240Kg safe Working Load) 2 section Electric , with manual backrest and support rails -PRH (LMWD)	31362	05056123840875
SM2670	Medicare Mobile Treatment Couches (240Kg safe Working Load) 2 section Electric , with Electric backrest and support rails -PRH (LMWD)	31362	05056123840882
SM3450	Medicare Mobile Treatment Couches (240Kg safe Working Load) 3 section Hydraulic , with manual backrest and support rails -PRH (LIBC)	42486	05056123803054
SM3460	Medicare Mobile Treatment Couches (240Kg safe Working Load) 3 section electric , with manual backrest and support rails -PRH (LIBC)	31362	05056123841049
SM3470	Medicare Mobile Treatment Couches (240Kg safe Working Load) 3 section electric , with electric backrest and support rails -PRH (LIBC)	31362	05056123841056
SM3650	Medicare Mobile Treatment Couches (240Kg safe Working Load) 3 section Hydraulic , with manual backrest and support rails -PRH (LMWD)	42486	05056123803207
SM3660	Medicare Mobile Treatment Couches (240Kg safe Working Load) 3 section Electric , with manual backrest and support rails -PRH (LMWD)	31362	05056123840837
SM3670	Medicare Mobile Treatment Couches (240Kg safe Working Load) 3 section Electric , with manual backrest and support rails -PRH (LMWD)	31362	05056123840844
SM3550	Medicare Standard 3 section couches (240KG Safe Working load) - hydraulic with manual backrest (Retractable Wheel Design)	42486	05056123800800
SM3560	Medicare Standard 3 section couches (240kg Safe working load) -electric with manual backrest (Retractable Wheel Design)	31362	05056123800954
SM3570	Medicare Standard 3 section couches (240KG Safe working load) - Electric with electric back rest (Retractable Wheel Design)	31362	05056123801258
MG3670	Innovation Standard 3 section couch (250Kg safe working Load) electric height, backrest and foot section (LMWD)	31362	05056123802002

SEERS MEDICAL LTD

Document Number: SM-000536-TC



Document Title: DoC - (MT) MDR Class I - Medicare Clinical Range

Effective date: 2024-04-05

Issue 2

MG3470	Innovation Standard 3 section couch (250Kg safe working Load) electric height, backrest and foot section (LIBC)	31362	05056123801852
MG3675	Innovation Deluxe 3 section couch (250Kg safe working Load) electric height, backrest and foot section (LMWD) and CPR facilities	31362	05056123802606
MG3475	Innovation Deluxe 3 section couch (250Kg safe working Load) electric height, backrest and foot section (LIBC) and CPR facilities	31362	05056123802453
MG3693	Innovation Deluxe Daycare(250Kg safe working Load) electric height, backrest and foot section (LMWD) and CPR facilities and auto levelling -PRH and HC	31362	05056123803504
MG3493	Innovation Deluxe Daycare(250Kg safe working Load) electric height, backrest and foot section (LIBC) and CPR facilities and auto levelling -PRH and HC	31362	05056123803351
MG3690	Innovation Deluxe Dialysis(250Kg safe working Load) electric height, backrest and foot section (LMWD) and CPR facilities and auto levelling -PRH and HC	47117	05056123803801
MG3490	Innovation Deluxe Dialysis(250Kg safe working Load) electric height, backrest and foot section (LIBC) and CPR facilities and auto levelling -PRH and HC	47117	05056123803658
SM9556	Medicare Multi-Couch- Single Footrest (240KG SWL) Hydraulic with Manual Backrest (RWD)	42486	05056123803955
SM9566	Medicare Multi-Couch- Single Footrest (240KG SWL) Electric with Manual Backrest (RWD)	31362	05056123804105
SM9576	Medicare Multi-Couch- Single Footrest (240KG SWL) Electric with Electric Backrest (RWD)	31362	05056123804402
SM0575	Medicare Multi-Couch- Dual Footrest (240KG SWL) Electric height and backrest with fold down armrest-PRH (RWD)	31362	05056123804709
SM0585	Medicare Multi-Couch- Dual Footrest (240KG SWL) Electric height, tilt and backrest fold down armrest-PRH and HC (RWD)	31362	05056123805003
SM0585D	Medicare Multi-Couch- Dual Footrest (240KG SWL) Deluxe model with Electric height, tilt and backrest fold down armrest-PRH and HC (RWD) with Base cover and matching operators chair .	31362	05056123841063
SM5555	Medicare Orthopaedic couches (240Kg SWL) Hydraulic with manual backrest (RWD)	42486	05056123805300
SM5565	Medicare Orthopaedic couches (240Kg SWL) Electric with manual backrest (RWD)	31362	05056123805454
SM5575	Medicare Orthopaedic couches (240Kg SWL) Electric with Electric backrest (RWD)	31362	05056123805751
SM5585	Medicare Orthopaedic couches (240Kg SWL) Electric height, tilt and backrest -PRH and HC (RWD)	31362	05056123806055

SEERS MEDICAL LTD

Document Number: SM-000536-TC



Document Title: DoC - (MT) MDR Class I - Medicare Clinical Range

Effective date: 2024-04-05

Issue 2

SM5585D	Medicare Deluxe Orthopaedic couches (240Kg SWL) Electric height, tilt and backrest -PRH and HC (RWD) with base cover , matching stool and accessory kit.	31362	05056123806352
SM9556P	Medicare phlebotomy couches Hydraulic with manual backrest pair of phlebotomy armrests- PRH (RWD)	42486	05056123806659
SM9566P	Medicare phlebotomy couches Electric with manual backrest pair of phlebotomy armrests- PRH (RWD)	10789	05056123806802
SM9576P	Medicare phlebotomy couches Electric with Electric backrest pair of phlebotomy armrests- PRH (RWD)	10789	05056123807106
SM9586P	Medicare phlebotomy couches Electric height , tilt and backrest pair of phlebotomy armrests- PRH and HC (RWD)	10789	05056123807403
SM3590	Medicare Echocardiology couches (240Kg SWL), Electric height , tilt and back rest with matching stool- PRH(RWD)	31362	05056123807700
SM3690	Medicare Echocardiology couches (240Kg SWL), Electric height , tilt and back rest with matching stool- PRH(LMWD)	31362	05056123808004
SM9686	Medicare Ultrasound Couches (240Kg SWL) Electric Height, tilt and backrest with manual foot section- PRH and HC(RWD)	62694	05056123808301
SM9686D	Medicare Ultrasound Couches (240Kg SWL) Deluxe model with base cover , Electric Height, tilt, backrest with manual foot section-PRH and HC(RWD) and matching operators Chair.	62694	05056123808905
SM9696	Medicare Ultrasound Couches (240Kg SWL) Electric Height, tilt and backrest and foot section-PRH and HC(RWD)	62694	05056123808608
SM9696D	Medicare Ultrasound Couches (240Kg SWL) Deluxe model with base cover , Electric Height, tilt, backrest, foot section-PRH and HC(RWD) and matching operators Chair.	62694	05056123809209
SM8553	Medicare Gynaecology Couches (240Kg SWL) Hydraulic with manual backrest and leg supports -PRH (RWD)	36065	05056123809506
SM8563	Medicare Gynaecology Couches (240Kg SWL) Electric with manual backrest and leg supports -PRH (RWD)	33324	05056123809650
SM8573	Medicare Gynaecology Couches (240Kg SWL) Electric with electric backrest and leg supports -PRH (RWD)	33324	05056123809957
SM8583	Medicare Gynaecology Couches (240Kg SWL) Electric height , tilt and electric backrest and leg supports - PRH (RWD)	33324	05056123810250
SM8583D	Medicare Deluxe Gynaecology Couches (240Kg SWL) Electric height , tilt and electric backrest, leg supports	33324	05056123810557

SEERS MEDICAL LTD

Document Number: SM-000536-TC



Document Title: DoC - (MT) MDR Class I - Medicare Clinical Range

Effective date: 2024-04-05

Issue 2

	with removable extension , base cover and matching operator chair PRH and HC (RWD)		
SM8593D	Medicare Deluxe Gynaecology Couches (240Kg SWL) Electric height , tilt and electric backrest, leg supports with fold down extension , base cover and matching operator chair PRH and HC (RWD)	33324	05056123810854
SM8543	GP Gynaecology Couches (240Kg SWL) Electric height, tilt and backrest with manual head section -PRH and HC (RWD)	33324	05056123811158
SM8543D	GP Gynaecology Couches Deluxe (240Kg SWL) Electric height, tilt and backrest, manual head section with base cover and matching chair -PRH and HC (RWD)	33324	05056123811455
SM2573	Medicare Bariatric 2 section Couches (325KG) Electric, with electric Back rest – 80Cm wide (RWD)	58419	05056123811752
SM2673	Medicare Bariatric 2 section Couches (325KG) Electric, with electric Back rest – 80Cm wide (LMWD)	58419	05056123812056
SM4542	Medicare Bariatric 2 section Couches (325KG) Electric, with electric Back rest – 105Cm wide (RWD)	58419	05056123812353
SM4642	Medicare Bariatric 2 section Couches (325KG) Electric, with electric Back rest – 105Cm wide (LMWD)	58419	05056123812650
SM3573	Medicare Bariatric 3 section Couches (325KG) Electric, with electric Back rest – 80Cm wide (RWD)	58419	05056123812957
SM3673	Medicare Bariatric 3 section Couches (325KG) Electric, with electric Back rest – 80Cm wide (LMWD)	58419	05056123813251
SM3584	Medicare Bariatric Drop End Couches (325Kg SWL) Electric height and backrest, dual foot sections -85cm Wide (RWD)	58419	05056123813558
SM3583	Medicare Bariatric Drop End Couches (325Kg SWL) Electric height and backrest, single electric foot section -85cm Wide (RWD)	58419	05056123813855

Certificate of Approval

This is to certify that the Management System of:

Seers Medical Ltd

Kenton Road, Debenham, IP14 6LA, United Kingdom

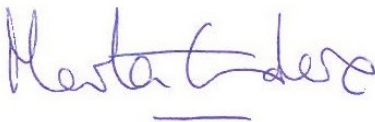
has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00010579

The scope of this approval is applicable to:

Manufacture and supply, Sales, Service and Support of Medical Treatment and examination couches, Patient positioning and Support surfaces, Transport trolleys, Medical seating and Associated accessories.



Marta Escudero

Regional Director, United Kingdom and Americas (UKAM)

Issued by: LRQA Limited



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