

Declaration of Conformity

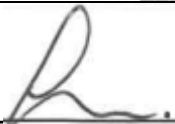
for SEERS MEDICAL Therapy Range

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

General Product Name:	Therapy
Legal Manufacturer: (Name on Label)	SEERS MEDICAL Limited, Kenton Road, Debenham, IP14 6LA, UK
Manufacturers SRN:	GB-MF-000003831
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Couches and tables for physiotherapy and Rehabilitation for patient
MDR Classification:	Class I Rule 1
Notified Body:	Not Applicable
EC Certificate:	Self-certification
Basic UDI:	50561238THERAPJF
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:** 2025-03-27 **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

Document Number: SM-000535-TC

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

Effective date: 2025-03-27

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Appendix I – Applicable Standards

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

Standard/Document Name	Description
EU MDR 2017/745	European 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	EMDN Code	UDI DI
ST1551A	Therapy Hygiene Table (240Kg SWL) LARGE hydraulic (RWD) 186cm*65cm	43494	V080202	05056123830654
ST1551B	Therapy Hygiene Table (240Kg SWL) Medium hydraulic (RWD) 152cm*65cm	43494	V080202	05056123829757
ST1651A	Therapy Hygiene Table (240Kg SWL) LARGE hydraulic (LMWD) 186cm*65cm	43494	V080202	05056123831101
ST1651B	Therapy Hygiene Table (240Kg SWL) MEDIUM hydraulic (LMWD) 152cm*65cm	43494	V080202	05056123830203
ST2557	Therapy 2 section couches (240Kg SWL) Hydraulic standard model (RWD)	32266	V08020101	05056123814159
ST2558	Therapy 2 section couches (240Kg SWL) Hydraulic Basic model (RWD)	32266	V08020101	05056123814609
ST2559	Therapy 2 section couches (240Kg SWL) Hydraulic plus model with armrests (RWD)	32266	V08020101	05056123815057
ST3556	Therapy 3 section Drop End couches (240Kg SWL) Hydraulic standard model (RWD)	32266	V08020101	05056123816856
ST3557	Therapy 3 section couches (240Kg SWL) Hydraulic standard model (RWD)	32266	V08020101	05056123815507
ST3558	Therapy 3 section couches (240Kg SWL) Hydraulic Basic model (RWD)	32266	V08020101	05056123815958
ST3559	Therapy 3 section couches (240Kg SWL) Hydraulic plus model with armrests (RWD)	32266	V08020101	05056123816405

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ST4552	Therapy Bobath Couches (250KG SWL) Hydraulic, 105CM wide (RWD)	32266	V08020101	05056123823151
ST4552W	Therapy Bobath Couches (250KG SWL) Hydraulic, 125CM wide (RWD)	32266	V08020101	05056123823304
ST5551	Therapy Mat Table (250Kg SWL) Hydraulic, 105CM (RWD)	32266	V08020101	05056123821959
ST5551W	Therapy Mat Table (250Kg SWL) Hydraulic, 125CM (RWD)	32266	V08020101	05056123822406
ST6557	Therapy Traction Couches Tables with traction mount (240KG SWL) Hydraulics with machine mount accessory (RWD)	32266	V08020101	05056123821201
ST6557P	Therapy Traction Couches Tables and with traction package (240KG SWL) Hydraulics with machine mount accessory (RWD)	32266	V08020101	05056123821652
ST7640	Therapy economy Tilt table (225KG SWL inc, patient Handgrip and harnesses (worktable optional) (IBC)	42577	V08020101	05056123826459
ST7640DL	Therapy economy Tilt table divided legs (225KG SWL inc, patient Handgrip and harnesses (worktable optional) (IBC)	42577	V08020101	05056123826756
ST7700	Shower Trolley (240KG) Standard Hydraulic (LMWD)	43494	V0899	05056123831804