Declaration of Conformity

for SEERS MEDICAL Sentego Range

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

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	SEERS MEDICAL SENTEGO RANGE
Legal Manufacturer: (Name on Label)	SEERS MEDICAL Ltd. Kenton Road, Debenham, Suffolk IP14 6LA, UK
Legal manufacturer SRN	GB-MF-000003831
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Patient transportation, examination with X-ray facilities and resuscitation within a variety of acute healthcare department
MDR Classification:	Class I rule I
Notified Body:	Not Applicable
EC Certificate	Self certification
Basic UDI	5056123SENTEGOVY
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN	MT-AR-000000234
Medical Device Regulation 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.

Name George Purnell **Position** Quality Manager

Signed  **Date** 29.11.2023 **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

Date 29 Nov 2023

EU Declaration of Conformity

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 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
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
TT200	Sentego 200 Stretcher with Hydraulic Height adjustment with hand operated Trendelenburg, manual backrest, foot section and CPR. Retracting backrest. (240KG SWL)	35892	05056123840936
TT400	Sentego 400 Stretcher with independent Hydraulic height adjustment at foot and head, giving foot operated Trendelenburg & reverse Trendelenburg, Manual CPR, retracting backrest, Fowler and vascular leg positions. (320KG SWL)	35892	05056123840929
TT600	Sentego 600 Stretcher with independent electric height adjustment at foot and head, giving electrically operated Trendelenburg & reverse Trendelenburg, electric and manual CPR, electric retracting backrest, electric leg section with manual adjustment for Fowler and vascular positions. (320KG SWL)	33000	05056123840912
TT600GO	Sentego 600 Stretcher with powered 5th wheel, independent electric height adjustment at foot and head, giving electrically operated Trendelenburg & reverse Trendelenburg, electric and manual CPR, electric retracting backrest, electric leg section with manual adjustment for Fowler and vascular positions. (320KG SWL).	33000	05056123840943

Version History

Version	Compiled by	Date	Description
1.0	J. Shaftoe	29.09.2022	First issue
2.0	G. Purnell	07 Nov 2023	Formatting, typing error & UDI-DI update
3.0	G. Purnell	29 Nov 2023	Minor administration update