



DECLARATION OF CONFORMITY

This is to confirm that the

Therapy SOS Unit

<u>Part No.</u>	<u>Description</u>
4550	Rail Mounted Therapy SOS unit
4560	Pole Clamp Therapy SOS Unit

Conforms to the EC Declaration of Conformity regarding Medical Devices as outlined in Annex II MDD 93/42 EEC consolidated 2007/47/EC of the Official Journal of the European Communities.

Therapy Equipment ensure and declare that the above products which have been classified as Class IIA (Annex IX Rule 11) are manufactured in conformity with technical documentation (Annex VII, Section 3) and meet the directive which apply to them.

Therapy Equipment declare that the Quality and Production Standards for the products conform to BS EN ISO 13485:2016, BS EN ISO 14971:2012, BS EN 62366-1:2015+A1:2020, BS EN ISO 15223-1:2016, BS EN 1041:2008+A1:2013.

EU Authorised Representative MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany

Therapy Equipment Ltd is exclusively responsible for this declaration of conformity and its contents.

Notified Body – British Standard Institute (Identification No. 2797)
CE Marking Certificate Number – CE 01847

The GMDN Code of the Product is 13325/37132.

Paul Robinson
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Therapy Equipment Ltd
1st Jan 2021