

EU DECLARATION OF CONFORMITY

Legal Manufacturer: The SpineCorporation Limited
Address: Millennium House, Peak Business Park, Foxwood Road, Chesterfield S41 9RF, UK
EU MF EUDAMED SRN: GB-MF-000001917
EU Authorised Representative: Ana del Campo, C/Enric Valor 12, BW54, 03540 Playa San Juan, Alicante, Spain
EU AR EUDAMED SRN: ES-AR-000001644
Product Name TechnoSpine TLSO Brace
Basic UDI 506017399TechnoSpineBM
Applied Directives European Commission Regulation (EU) No. 2017/745
Classification Rules Class 1 Medical Device, Rule 1 – As defined by Regulation (EU) 2017/745, AnnexVIII
GMDN Code 66086 Multiple Spinal Region Orthosis

"Legal Manufacturer" herewith declares that the above-mentioned device meets all applicable provisions of the European Commission Regulation (EU) No. 2017/745. The above-mentioned device meets the General Safety and Performance requirements as defined in Annex 1.

"Legal Manufacturer" has implemented measures assuring that SpineCor is safe and fulfils the essential requirements of Annex II and Annex III, (Technical Documentation) of the European Commission Regulation (EU) No. 2017/745.

"Legal Manufacturer" has instituted and keeps up to date a Quality Management Systems in line with the Harmonised Standard ISO13485-2016. Procedures are in place to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by the manufacturer.

This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer. I, the undersigned, am fully responsible for all the information provided in this declaration and I fully understand and acknowledge that it is an offence to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory on Behalf of
The SpineCorporation Limited:



Name & Position Within Company:

Helen Wainwright
Operations Manager

Date and place of issue:

25th January 2022 within the territory of the United Kingdom

