

Declaration of Conformity

Product Name	Paraguard Excel Rescue Stretcher	Ref No:	DOC – PARA
Product Code/GTIN No	010795401	Issue No:	2
Intended Use	Rescue/Extraction Device	Review Date:	May 2021
Product Classification	Class I Medical Device as per Rule 1 Chapter III Annex VIII MDR 2017/745		
Manufacturers Name	Ferno (UK) Limited		

Manufacturers Address & UKCA Representative		EU Authorised Representative (if applicable)	
Ferno House, Stubs Beck Lane, Cleckheaton, West Yorkshire. BD19 4TZ United Kingdom Tel: +44 (0) 1274 851999 www.ferno.co.uk		Ferno s.r.l. Via B. Zallone, 26, Pieve di Cento 40066 Bologna Italy Tel: +39.051.6860028 www.ferno.it	

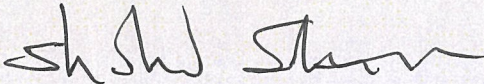
LOT ID/UDI prefix TBA ##### **Date of First Manufacture** 2007

Serial Numbers are identified on the Manufacturing and Inspection Record and/or the Customer Database. These should be referenced in all communication as customer variants, including SM & PN, affect the Product Code reference.

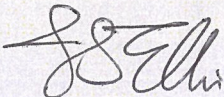
The undersigned, on behalf of Ferno (UK) Ltd, hereby declare that the medical device specified above complies with:

- General Safety and Performance Requirements within *Annex I* of EC Regulation 2017/745,
- BS EN 1865-1 Patient handling equipment used in road ambulances. General stretcher systems and patient handling equipment
- Registered with the UK Competent Authority (MHRA) and additional designated standards referenced to compile the technical documentation detailed in the 'Technical File' as held by the Engineering & Design Manager at the above address.

This declaration is compiled in accordance with *Article 19* and *Annex IV* of EC Regulation 2017/745 and supported by a Quality Management System which has been assessed and approved to BS EN ISO 9001:2015 by ACM-CCAS Quality Assurance assessment services.

	16 June 2021	Shahid Saleem
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<i>Signed: Engineering & Design Manager</i>	<i>Dated</i>	<i>Print Name</i>
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	16 June 2021	Jon Ellis
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<i>Signed: Managing Director</i>	<i>Dated</i>	<i>Print Name</i>
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