

Declaration of Conformity

Product Name	Harrier Trolley	Ref No:	DOC – HAR
Product Code/GTIN No	005073021	Issue No:	2
Intended Use	Patient Transportation	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)
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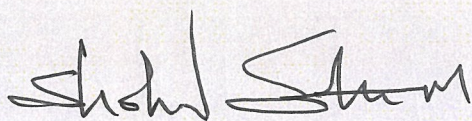
LOT ID/UDI prefix	HAR/HXL #####	Date of First Manufacture	2011
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Serial Numbers are identified on the Manufacturing and Inspection Record and/or the Customer Database. These should be referenced in all communication as customer variants, including SM & 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 1865-2 Patient handling equipment used in road ambulances. Power assisted stretcher
- BS EN 1789 Road Ambulances and their 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.



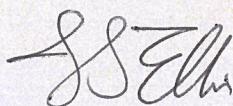
16 June 2021

Shahid Saleem

Signed: Engineering & Design Manager

Dated

Print Name



16 June 2021

Jon Ellis

Signed: Managing Director

Dated

Print Name