



EC Declaration of Conformity

Manufacturers Name:	Ferno Slovakia s.r.o.
Manufacturers Address:	Bošáca 893 / 913 07 / Slovakia
SRN (Single Registration Number):	SK-MF-000001474
Authorized Representative 1 (EU AUTHORIZED REPRESENTATIVE)	Ferno S.r.l. via B.Zallone, n.26,40066 Pieve di Cento, Bologna, Italy +39.051.6860028 www.ferno.it
Authorized Representative 2 (UKCA REPRESENTATIVE)	Ferno House Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ United Kingdom +44 (0) 1274 851999 www.ferno.co.uk
Basic UDI-DI:	8588008129FS_stretcherMY
Name of the Device (s):	CHAIR-STRETCHER RS-5 FLAT-STRETCHER RS-6
Product code:	60-4300-001; 60-4300-001/AW 60-4310-001; 60-4310-001/AW
Classification:	Class I
Notified Body name:	N/A
Notified Body Address:	N/A
Notified Body Identification number:	N/A
Conformity assessment route:	Ferno Slovakia s.r.o. uses the following procedures for the CE- labeling of their products according the Regulation MDR 2017/745: EN 1865-1; EN 1789
	<u>Class I:</u> EC conformity declaration according to Annex IV + Annex VIII of MDR 2017/745
Form Name: EC DoC 2017/745 EU	Page 1 of 3





This declaration of conformity is issued under the sole responsibility of Ferno Slovakia s.r.o. We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by 3EC, Slovakia, August 2020.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and date of issue:

Silvia Vančová Managing Director

Bošáca, 21.5.2021





Attachment nr.1 to declaration of conformity CHAIR-STRETCHER RS-5; FLAT-STRETCHER RS-6

CHAIR-STRETCHER RS-5; FLAT-STRETCHER RS-6

Part Number	Product description	GTIN (UDI-DI)
60-4300-001	CHAIR-STRETCHER RS-5 (PACKED)	8588008129814
60-4300-001/AW	CHAIR-STRETCHER RS-5 with folding headrest (PACKED)	8588008129821
60-4310-001	FLAT-STRETCHER RS-6 (PACKED)	8588008129838
60-4310-001/AW	FLAT-STRETCHER RS-6 with folding headrest (PACKED)	8588008129845