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) CE	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) UKCA	Ferno House Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ United Kingdom +44 (0) 1274 851999 www.ferno.co.uk
Basic UDI-DI:	8588008129FAST/FSTChair5Y
Name of the Device (s):	FAST/FST chairs
Product code:	60-4100-001; 60-4110-001; 60-4120-001; 60-4130-001
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: ISO 1865-4; ISO 1789 2007+ A2 2012 Class I: EC conformity declaration according to Annex IV + Annex VIII of MDR 2017/745

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:



Silvia Vančová
Managing Director

Place and date of issue:

Bošáca, 31.3.2021

FAST/FST chairs

Part Number	Product description	GTIN (UDI-DI)
60-4100-001	FAST CHAIR (PACKED)	8588008129012
60-4100-001/H	FAST CHAIR (PACKED) with handle	8588008129029
60-4100-001/H/F	FAST CHAIR (PACKED) with handle, k. footbar	8588008129036
60-4100-001/H/F/A	FAST CHAIR (PACKED) with handle, k. footbar, armrests	8588008129043
60-4110-001	FST CHAIR (FIXED TRACK) (PACKED)	8588008129050
60-4110-001/H	FST CHAIR (FIXED TRACK) with handle (PACKED)	8588008129067
60-4110-001/H/F	FST CHAIR (FIXED TRACK) with handle, k. footbar (PACKED)	8588008129074
60-4110-001/H/F/A	FST CHAIR (FIXED TRACK) with handle, k. footbar, armrests (PACKED)	8588008129081
60-4110-001/H/F/4PR/M	FST CHAIR (FIXED TRACK) with handle, k. footbar, 4 bod.rest., mesh(PACKED)	8588008129098
60-4120-001	FAST CHAIR (REMOVABLE STAIR TRACK) (PACKED)	8588008129104
60-4120-001/H	FAST CHAIR (REMOVABLE STAIR TRACK) with handle (PACKED)	8588008129111
60-4120-001/H/F	FAST CHAIR (REMOVABLE STAIR TRACK) with handle, k. footbar (PACKED)	8588008129128
60-4120-001/H/F/A	FAST CHAIR (REMOVABLE STAIR TRACK) with handle, k. footbar, armrests (PACKED)	8588008129135
60-4130-001	FAST CHAIR (REMOVABLE POWERTRAXX) (PACKED)	8588008129142
60-4130-001/H	FAST CHAIR (REMOVABLE POWERTRAXX) with handle (PACKED)	8588008129159
60-4130-001/H/F	FAST CHAIR (REMOVABLE POWERTRAXX) with handle, k. footbar (PACKED)	8588008129166
60-4130-001/H/F/A	FAST CHAIR (REMOVABLE POWERTRAXX) with handle, k. footbar, armrests (PACKED)	8588008129173
60-4140-001	FST CHAIR (FIXED PWRTXX) (PACKED)	8588008129180
60-4140-001/H	FST CHAIR (FIXED PWRTXX) with handle (PACKED)	8588008129197
60-4140-001/H/F	FST CHAIR (FIXED PWRTXX) with handle, k. footbar (PACKED)	8588008129203
60-4140-001/H/F/A	FST CHAIR (FIXED PWRTXX) with handle, k. footbar, armrests (PACKED)	8588008129210