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:	8588008129600102StretchG7
Name of the Device (s):	S-2108 POLE STRETCHER
Product code:	60-0102-005; 60-0102-006; 60-0102-007; 60-0102-008
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 1865-1; 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, 24.5.2021

S-2108 POLE STRETCHER

Part Number	Product description	GTIN (UDI-DI)
60-0102-005	S-2108-AF- 206 POLE STRETCHER	8588008129456
60-0102-006	S-2108-AF-229 POLE STRETCHER, (PACKED)	8588008129463
60-0102-007	S-2108-A-206 POLE STRETCHER	8588008129470
60-0102-008	S-2108-A-229 POLE STRETCHER, (PACKED)	8588008129487