

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:	8588008129Ferno11StretcL8
Name of the Device (s):	11 FERNO STRETCHER
Product code:	60-0104-004; 60-0104-007; 60-0104-009; 60-0104-009/G; 60-0104-015; 60-0104-016; 60-0104-016/ger.; 60-0104-018; 60-0104-020
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 <u>Class I:</u> 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 the 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, 21.5.2021

Attachment nr.1 to declaration of conformity 11 FERNO STRETCHER**11 FERNO STRETCHER**

Part Number	Product description	GTIN (UDI-DI)
60-0104-004	11 FERNO STRETCHER BLACK (PACKED)	8588008621004
60-0104-007	11 FERNO STRETCHER BLACK (PACKED)	8588008621028
60-0104-009	11 FERNO STRETCHER BLACK WITH FOOT PLATE (PACKED)	8588008621035
60-0104-009/G	11 FERNO STRETCHER GREY WITH FOOT PLATE (PACKED)	8588008621042
60-0104-015	11 LOCKING HINGE BLACK VINYL COVER, STRETCHER (PACKED)	8588008621066
60-0104-016	11-T FERNO STRETCHER (PACKED)	8588008129494
60-0104-016/ger.	11-T FERNO STRETCHER (PACKED)	8588008129500
60-0104-018	11-K FERNO STRETCHER GREY (PACKED)	8588008129517
60-0104-020	11-K DUOFOLD FERNO STRETCHER BLK (PACKED)	8588008129524