EU Declaration of Conformity

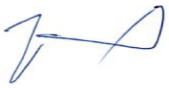
Manufacturers Name:	Ferno Slovakia s.r.o.
Manufacturers Address:	Bošáca 893 / 913 07 / Slovakia
SRN (Single Registration Number):	SK-MF-000001474
Authorized Representative (UKCA REPRESENTATIVE)	Ferno House Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ United Kingdom +44 (0) 1274 851999 www.ferno.co.uk
Basic UDI-DI:	8588008129F2StretcherHS
Name of the Device (s):	F2 MONOBLOC F2 TRANSPORTER F2 STRETCHER
Product code:	F2 MONOBLOC 60-0303-002; 60-3000-001; 60-0303-003 60-0304-001; 60-0305-001; 60-0306-001 60-0306-002; 60-0309-001; 60-0309-002 60-0309-003; 60-0309-004; 60-0309-005 60-0312-001; 60-0312-002; 60-0312-003 60-0312-004; 60-0312-005; 60-0323-001 60-0323-001-BLK; 60-0303-001_BLK 60-0324-001; 60-0324-002; 60-0325-001 F005025002ACP F2 TRANSPORTER 60-0300-001; 60-0300-002; 60-0311-001 60-0311-002; 60-0313-001; 60-0314-001 60-0321-001; 60-0321-011; 60-0322-001 F2 STRETCHER 60-0301-001; 60-0301-001_RED; 60-0301-002; 60-0302-001; 60-0307-001; 60-0308-001 60-0308-001/RED; 60-0308-001/SDIS21 60-0308-002; 60-0308-003; 60-0310-002

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. Ferno Slovakia s.r.o. hereby declares that the products conform to: EN 1865-1:2010+A1:2015 and EN 1789:2020. Class I: EU conformity declaration according to Annex IV + Annex VIII of MDR 2017/745 This DoC is issued based on the ISO 13485 Certification.

This Declaration of Conformity is issued by Ferno Slovakia s.r.o.
We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices.

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

Signature:



Silvia Vančová
Managing Director

Place and date of issue:

Bošáca, 26.2.2025

Attachment nr.1 to declaration of conformity F2 MONOBLOC, F2 TRANSPORTER, F2 STRETCHER

F2 MONOBLOC

Product Number	Product description	GTIN (UDI-DI)
60-0303-001_BLK	MONOBL. F2 4P 59CM (H56) BLACK	8588008621981
60-0303-002	MONOBL. F2 4P 59CM (H56) (FPernas) BLACK	8588008621981
60-0303-003	MONOBL. F2 4P 59CM (H56) BB (BACKBOARD) BLACK	8588008621981
60-0304-001	MONOBL. F2 5P 59CM (H56) BLACK	8588008621981
60-0305-001	MONOBL. F2 4P 54CM (H50) BLACK	8588008621981
60-0306-001	MONOBL. F2 5P 54CM (H50) BLACK	8588008621981
60-0306-002	MONOBLOC F2 -BB - 3 PART H50	8588008621981
60-0309-001	MONOBLOC F2 3P 59CM (H56) BLK + RESTR. PP	8588008621981
60-0309-002	MONOBLOC F2 3P 54CM (H50) BB BLK	8588008621981
60-0309-003	MONOBL. F2 3PART 59CM (H56) BB, BLK PIN	8588008621981
60-0309-004	MONOBL. F2 3PART 59CM (H56) BB YELLOW	8588008621981
60-0309-005	MONOBL. F2 3P 54CM (H50) BLACK	8588008621981
60-0312-001	MONOBLOC F2, 3PARTS, H56 cm ,W/O third fix., W/O SIDERAILS, W/2 RESTRAINTS	8588008621981
60-0312-002	F-2 MONOBLOC - 3 PARTS, H56 cm	8588008621981
60-0312-003	F2M - MONOBLOC 3 PARTS WITH 3RD FIXATION POINT	8588008621981
60-0312-004	MONOBLOC F2, 3PARTS, H56 cm ,W/O third fix., W/O SIDERAILS, W/2 REST. W/BLUE MATTRESS 4P	8588008621981
60-0312-005	MONOBLOC F2 3P H56 w/THIRD FIX	8588008621981
60-0323-001	MONOBLOC F2M 4P H69 LH 2SW S/S PIN	8588008621981
60-0323-001-BLK	MONOBL.F2M 4P, 69CM, LH 2SW, BLK PIN	8588008621981
60-0324-001	MONOBLOC F2M 4 PART 69 cm HEIGHT 4SW	8588008621981
60-0324-002	MONOBL. F2 4SW 4P 69CM (H69) BLACK witl locking leg system	8588008621981
60-0325-001	MONOBLOC F2 5 PART 69CM LH TIPO STAND	8588008621981
60-3000-001	F2 MONOBLOC 56/60CM W/RESTR.+MATT.	8588008621981
F005025002ACP	MONOBLOC F2M 4P 69CM HEIGHT 4SW LLS	8588008621981

F2 TRANSPORTER

Product Number	Product description	GTIN (UDI-DI)
60-0300-001	TRANSPORTER F2 59CM (H56) S/S PIN	8588008621127
60-0300-001	TRANSPORTER F2 59CM (H56) BLACK	8588008621127
60-0300-002	TRANSPORTER F2 59CM (H56) YELLOW	8588008621127
60-0311-001	TRANSPORTER F2 54CM (H50) BLACK	8588008621127
60-0311-002	TRANSPORTER F2 54CM (H50) YELLOW	8588008621127
60-0313-001	TRANSPORTER F2 4SW 59CM (H56) BLACK	8588008621127
60-0314-001	TRANSPORTER F2 E 59CM (H56) ELECTRIC CHARRIOT RED	8588008621127
60-0321-001	TRANSPORTER F2 69H 2SW S/S PIN	8588008621127
60-0321-001	TRANSPORTER F2 69CM (H69) BLK PIN	8588008621127
60-0321-011	TRANSPORTER F2M 11K 69CM BLACK	8588008621127
60-0322-001	TRANSPORTER F2 4SW 69CM (H69) BLACK	8588008621127

F2 STRETCHER

Product Number	Product description	GTIN (UDI-DI)
60-0301-001	STRETCHER F2 - 4 PART BLACK	8588008621073
60-0301-001	STRECHER F2 - 4 PART, BB BACK. RED	8588008621073
60-0301-001_RED	STRETCHER F2 5P BB RED	8588008621073
60-0301-002	STRETCHER F2 5P BB BLACK	8588008621073
60-0302-001	STRETCHER F2 5P BLACK	8588008621073
60-0307-001	F-2 STRET. 5P W/BACKREST W/O 3 RD FAST.	8588008621073
60-0308-001	STRETCHER F2 3P BB BLACK	8588008621073
60-0308-001/RED	F-2 STRETCHER 3 PART BB, RED	8588008621073
60-0308-001/SDIS21	F-2 STRETCHER 3 PART BB -SDIS 21	8588008621073
60-0308-002	STRETCHER F2 3P BB YELLOW	8588008621073
60-0308-003	STRETCHER F2 4P YELLOW	8588008621073
60-0310-002	STRETCHER F2 4P BB BLACK	8588008621073

Related Accessories:

Product Number	Product description	GTIN (UDI-DI)
60-0150-003	10G F2 LOCKING DEVICE	8588008621721
65-1300-001	INSTRUMENT TRAY Nº8 566X516 PRETO	8588009265351
65-1300-002	INSTRUMENT TRAY Nº9 566X516 PRETO	8588009265351
65-1300-003	INSTRUMENT TRAY 436x516 PRETO	8588009265351
65-1301-001	IV POLE WITH EXTRA SUPPORT	8588009265375
65-1301-002	FOLDABLE IV POLE	8588009265375
65-1301-003	IV POLE	8588009265375
65-1302-009	MATTRESS Large Body Surface Black Grafite	8588009265399
65-1302-010	MATTRESS LBS, 2 SIdes Kit for Standard Mattress	8588009265399
65-1306-001	OXYGEN CYLINDER HOLDER	8588009265405
65-1306-002	ARTICULATED OXYGEN BOTTLE SUPPORT	8588009265368
65-1307-001	KIT MONOBLOC F2 3P DGPC BLACK	8588009265412
65-1307-002	KIT LOCKS FOR INSTRUMENTS TRAY	8588009265351
65-1308-001	Large Body Surface Stretcher	8588009265382