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 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:	8588009265F3SMonobloc2K
Name of the Device (s):	MONOBLOC F3S
Product code:	60-0340-004
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 1865-1:2010+A1:2015; EN 1789:2020 Class I: EU 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.

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

Signature:

Silvia Vančová
Managing Director

Place and date of issue:

Bošáca, 7.11.2023

Attachment nr.1 to declaration of conformity MONOBLOC F3S

MONOBLOC F3S included Accessories

Part Number	Product description	GTIN (UDI-DI)
60-0340-004	MONOBLOC F3S, 4P	8588009265474
63-4400-001	4-POINT RESTRAINT + 2X RESTRAINT 1PC 180CM	8588008621202
65-0358-002	PAD, MATTRESS BLACK	8588009265313
65-0358-101	MATTRESS F3 BLACK, WELDED	8588009265443
65-4346-001	HEADREST	8588008621158
60-0150-003	10G F2 LOCKING DEVICE	8588008621721