

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:	8588008129600112Scoops8L
Name of the Device (s):	SCOOP S-265
Product code:	60-0112-001; 60-0112-002; 60-0112-005; 60-0112-006; 60-0112-007; 60-0112-014
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 to the Regulation MDR 2017/745: EN 1865-1; EN 1789 <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 SCOOP S-265

SCOOP S-265

Part Number	Product description	GTIN (UDI-DI)
60-0112-001	SCOOP S-265 BLUE (PACKED)	8588008129746
60-0112-002	SCOOP S-265 ARMY GREEN	8588008621325
60-0112-005	SCOOP S-265 SILVER (PACKED)	8588008129753
60-0112-006	SCOOP S-265 ANODIZED (PACKED)	8588008129760
60-0112-007	SCOOP S-265 DARK GREY (PACKED)	8588008129777
60-0112-014	SCOOP S-265 GREEN, St. JOHN AMBULANCE (PACKED)	8588008129784