# *EC Declaration of Conformity*

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|---|---|
| **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.<br>via B.Zallone, n.26,40066<br>Pieve di Cento, Bologna, Italy<br>+39.051.6860028<br>www.ferno.it |
| **Authorized Representative 2 (UKCA REPRESENTATIVE)** UKCA | Ferno House<br>Stubs Beck Lane,<br>Cleckheaton,<br>West Yorkshire,<br>BD19 4TZ<br>United Kingdom<br>+44 (0) 1274 851999<br>www.ferno.co.uk |
| **Basic UDI-DI:** | 8588008129600101SplintsE5 |
| **Name of the Device (s):** | TRACTION SPLINT |
| **Product code:** | 60-0101-003; 60-0101-006; 60-0101-007 |
| **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<br><br>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, 21.5.2021

**TRACTION SPLINT**

| Part Number | Product description | GTIN (UDI-DI) |
|---|---|---|
| 60-0101-003 | 441 TRACTION SPLINT SET, ADULT+PEDIATRIC (PACKED) | 8588008129548 |
| 60-0101-006 | S-2444 TRACTION SPLINT, ADULT (PACKED) | 8588008129555 |
| 60-0101-007 | S-2443 TRACTION SPLINT, PEDIATRIC (PACKED) | 8588008129562 |