



EC Declaration of Conformity

Manufacturer: **FootScientific Inc.**

Address: 76 W 13775 S #4
Draper, UT (Utah) 84020
United States of America
Web site: www.footscientific.com

Medical product: **Elevate Drop Foot Brace 2.0**

Device Trade Name: **Elevate™**

REF: **100.60**

Basic UDI-DI: **0850029786Elevate360HB**

Intended purpose: To create stable dorsiflexion in foot and ankle in the absence of one's own wilful capacity. For use with a variety of shoe styles and to emphasize comfort and style over traditional AFO devices.

Classification: Medical product Elevate Drop Foot Brace 2.0 is classified as Class I by Rule 1 of Annex VIII, Medical Device Regulation – Regulation (EU) 2017/745.

We, FootScientific Inc. ensure and declare under our sole responsibility that the listed products to which this Declaration of Conformity relates are in conformity and meet the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, which apply to them and covered by CE mark.

Medical product Elevate Drop Foot Brace 2.0 is compliant with the required technical documentation, it is subject to the procedure set out in Annex II and Annex III according to Article 52, section 7 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

Conformity assessment route: According to Annex II and Annex III.

We hereby warrant and declare that the medical product Elevate Drop Foot Brace 2.0, which is on the market, is marked by CE marking, belongs to Class I, and meets requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

Harmonized standards and regulations: *EN ISO 13485:2016, EN ISO 15223-1:2016, EN 1041:2008/A1:2013, EN ISO 14971:2019, IEC 62366-1:2015, EN 62366:2008/A1:2015, ISO 10993-1:2018, ASME Y14.5-2018, MEDDEV 2.7/1 Rev. 4, MEDDEV 2.12/2 Rev. 2, MEDDEV 2.12-1 Rev. 8.*

EU Authorized Representative: MedNet EC-REP GmbH

Address: Borkstraße 10, 48163 Münster, Germany

Utah 84020, USA, Date: 05/12/21

Name and Role of Authorized Signatory: **CEO, Chris R. Hughes**

Authorized Signature: _____

A handwritten signature in blue ink, appearing to be "CRH", written over a horizontal line.