CE

EU Declaration of Conformity

EU Medical Device Regulation 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning Medical Devices as transposed into European national law by the member states

We herewith declare that the above mentioned products meet the provisions of the EU Medical Device Regulation 2017/745. All supporting documentation is retained under the premises of the manufacturer.

Product name : Ankle Foot Orthosis
Model name : AF SERVO

- Manufacturer : Uditel Co. Ltd.
- Address : Business Incubating Center 907, 17, Wauan-gil, Bongdam-eup, Hwaseong-si, Gyeonggi-do, 18323, Republic of Korea

- European Representative : Obelis S.A.
- Address: Boulevard Général Wahis 53, 1030 Brussels, Belgium

- EMDN : Y061206 (Ankle/foot Orthosis)
- SRN : KR-MF-000022417
- GMN(Basic UDI-DI): 880987816AFO20130101XA

- Classification : Class I (Rule 1 of MDR EU 2017/745 Annex VIII)
- Conformity assessment procedure for CE marking : Annex IV, MDR EU 2017/745
- Notified Body : Not Applicable for Class I

- Standards Applied : EN ISO 9001[2015], EN ISO 14971[2019], EN 62366-1[2015], EN 1041 [2013], EN ISO 15223-1[2016], MED DEV2.12-1 Rev.8, MEDDEV 2.7.1 Rev.4

Start of CE-marking : August 8, 2018
Place, Date of issue : Hwaseong-si, Republic of Korea, Feb. 11, 2022.

Signature :

President
President of UDITEL Co. Ltd

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