SPANLINK INTERNATIONAL

EU Declaration of Conformity

The following description for the medical device,

Device information	*Description*
Registered trade name and address	*Span Link International LLC* *28 West Jefryn BLVD., Suite C, Deer Park, NY 11729, USA* *Tel:+1-631-392-1434*
Authorized representative	*Y. Sung Handelsvertretung* *Duesselthaler Str. 24, 40211 Duesseldorf Germany*
Common device name	*Ankle / Foot Orthosis*
Product and trade name	*XCELTRAX®*
UMDNS code	***17873**: Ankle / Foot Orthosis*
GMDN code	***36206**: Ankle / Foot Orthosis*
Single Registration Number (SRN)	***DIMDI register # 00314114***
Risk class of the device	*Class I*
Basic UDI-DI	(01)00190446702191(11)200716(10)00041(21)00041
Common Specification (CS) references	- *XCELTRAX® ANKLE* - *XCELTRAX®* - *XCELTRAX® AIR ANKLE* - *XCELTRAX® AIR* - *XCELTRAX® AIR ANKLE REPLACEMENT LINER* - *XCELTRAX® AIR REPLACEMENT LINER* - *XCELTRAX® ANKLE REPLACEMENT LINER* - *XCELTRAX® REPLACEMENT LINER*
Intended purpose (GMDN definition)	*An externally-applied appliance or apparatus intended to encompass the ankle joint, or the ankle and foot, to support, align, prevent, or correct orthopaedic deformities/injuries or to improve function of the ankle and/or foot; it may also be intended to offload and redistribute foot pressures that affect pedal circulation to improve blood flow and help heal diabetic foot ulcers or postsurgical wounds. It is made of metal, synthetic, and/or textile materials and may include customizable plantar inserts. This is a single-patient device that can be reapplied to the patient during the treatment period (reusable) before being discarded.*
Conformity assessment procedure performed and identification of the	*Quality Management System* *EN ISO 13485:2016 by DNV GL PRESAFE AS*

Issued date: August 27, 2020
Version: V1.0

certificates issued by notified body, if applicable	
Name and identification number of the notified body, if applicable	*DNV GL PRESAFE AS* *Certificate Number: 248800-2017-AQ-RGC-NA-PS Rev. 2.0*

that is covered by the present declaration is in conformity with the Medical Device **Regulation 2017/745/EU** as amended by **2020/561/EU** and, if applicable, with any other relevant Union legislation that provides for the issuing of this EU declaration of conformity. The device is in conformity with conformity assessment procedure for **Class I devices** that should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. Thus, manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing an EU declaration of conformity referred to in Article 19 "EC declaration of conformity" after drawing up the technical documentation set out in Annexes II and III of the **Regulation**.

For the evaluation regarding Class I device **(**Risk class in accordance with the Rule 1 set out in Annex VIII of the **Regulation**), the following harmonized standards are applied:

- *EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *EN ISO 14971:2012 Medical devices —Application of Risk Management*
- *EN ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
- *EN 62366-1:2015 Medical devices Part 1-- Application of usability engineering to medical devices*

The following Union authorized representative is stated to the declaration:

Y. Sung Handelsvertretung
Duesselthaler Str. 24, 40211 Duesseldorf Germany
(Company name / Registered place of business)

The following person is exclusively responsible for the compliance of declaration:

Span Link International LLC
28 West Jefryn BLVD., Suite C, Deer Park, NY 11729, USA
(Manufacturer's name/ Registered address)

Vincent A Benenati / CEO *August 27, 2020*
(Name/Function) (Legal Signature) (Date of issue)