# EU Declaration of Conformity

**Span Link International LLC**
**28 Jefryn Blvd, Suite C**
**11729 Deer Park, NY, USA**
**Single Registration Number (SRN): US-MF-000012261**

Hereby declares under own responsibility, that the following products comply with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

<table>
<tr><td>Product name</td><td>
<table>
<tr><th>Product Name</th><th>Version</th><th>DARCO Ref</th></tr>
<tr><td>Air Pump Walker</td><td>High Shaft</td><td>APW0, APW1, APW2, APW3, APW4</td></tr>
<tr><td>Air Pump Walker</td><td>Short Shaft</td><td>APWS0, APWS1, APWS2, APWS3, APWS4</td></tr>
<tr><td>Air Pump Walker Achill</td><td>Achill</td><td>APWA0, APWA1, APWA2, APWA3, APWA4</td></tr>
<tr><td>Air Pump Walker Achilles Wedges</td><td>-</td><td>APWAW</td></tr>
</table>
</td></tr>
<tr><td>Basic UDI-DI</td><td>1230000153APW0BF</td></tr>
<tr><td>Intended purpose</td><td>Air Pump Walker<br>Lower leg foot orthosis for immobilization in a given position.<br><br>Air Pump Walker Achill<br>This medical device is a lower leg foot orthosis for complete immobilization of the lower leg and foot region in a defined, adjustable position.<br><br>Indications Air Pump Walker/ High Shaft:<br>- Pre-operative/ post-traumatic immobilization in case of damage to the bone/ capsule and ligament structures of the foot/ ankle;<br>- Soft tissue injury;<br>- Stable foot and/ or ankle fractures;<br>- Severe sprains grade II and III.<br>Indications Air Pump Walker/ Short Shaft:<br>- Pre-operative/ post-traumatic immobilization in case of damage to the bone/ capsule and ligament structures of the foot/ ankle;</td></tr>
</table>



Issued date: July 18, 2023

| | |
|---|---|
| | - Soft tissue injury;<br>- Stable foot and/ or ankle fractures;<br>- Severe sprains grade II.<br>*Indications Air Pump Walker Achill:*<br>- Achilles tendon ruptures (due to using *Air Pump Walker Achilles Wedges*)<br>*Contra-Indications:*<br>- Unstable fractures;<br>- Skin diseases in the body part treated;<br>- Sensitivity disorders. |
| Medical Device Classification | *Class I Device* according to Rule 1 in the Annex VIII, Chapter III, MDR 2017/745/EU as amended by 2020/561/EU |
| Conformity assessment procedure | *Annexes II and III of MDR* (Technical Documentation and PMS documentation). |

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485 and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

| | |
|---|---|
| European authorized representative | *Y. Sung Handelsvertretung*<br>*Toulouser Allee 9,*<br>*40211 Düsseldorf, Germany* |

Date of issue: July 18, 2023

(Compiled and released)
Vincent A Benenati, CEO, Span Link International LLC