



## DECLARATION OF CONFORMITY

**Re: Registration to BS EN ISO 13485:2016**

**Manufacturer's Name:** Silipos Holding LLC.

**Manufacturer's Address:** 7049 Williams Road  
Niagara Falls, NY 14304  
USA

**Authorized European Representative:**  
WMDE b.v.  
Bergerweg 18  
6085 AT Horn  
The Netherlands

**Name of Device Family:** Class I Medical Device (FDA Registered), Rule 1 per MDR (EU) 2017/745, Annex VIII

**Conformity Assessment Route:** Conformity Declaration. Per MDR (EU) 2017/745, Annex IV

**Type of Device:**

Class I non-sterile: padded sheaths, socks, and digital wraps used for cushioning and eliminating abrasions when used with orthotic and prosthetic medical devices and also in the area for scar management in accordance to ISO 13485:2016.

**Serial#/Batch#:** Silipos maintains traceability for select products that contain serial numbers. Every batch of product has its own distinct batch (lot) number

**Year of Manufacture:** Silipos products can be manufactured multiple times during the course of a year and may remain in inventory depending on sales. The date of manufacture is listed on all products.


**Standards Applied:** A list of Harmonized Standards for which documented evidence for compliance can be provided and are included in the Technical Files

I, the undersigned hereby declare that the medical device family (ies) indicated in the technical file and specified above conform with the relevant Essential Requirements of

Regulation (EU) 2017/745 for medical devices. This declaration is issued under the sole responsibility of the manufacturer.

Place: Silipos Holding LLC.  
7049 Williams Road  
Niagara Falls, NY 14304

Name: Thomas S. Bickelman  
Title: Operations Manager

Signature:  Date: 5.26.2021

**Product List Class I Medical Device 880.6280-KYS – Insoles, Medical**

PRODUCT	ARTICLE NUMBER	CLASSIFICATION	Product Code
Wonderspur Soft Heel Cup, Small	4500	880.6280	KYS
Wonderspur Soft Heel Cup, Medium	4501	880.6280	KYS
Wonderspur Soft Heel Cup, Large	4502	880.6280	KYS
Wonderspur Soft Heel Cup, X-Large	4503	880.6280	KYS
WonderCup Dual-Density Heel Cup, Small	4504	880.6280	KYS
WonderCup Dual-Density Heel Cup, Medium	4505	880.6280	KYS
WonderCup Dual-Density Heel Cup, Large	4506	880.6280	KYS
WonderCup Dual-Density Heel Cup, X-Large	4507	880.6280	KYS