



## 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 890.6450 (IPM)-Cover, Limb**

Symes Gel Liner, 1/Pkg, One Size	1302	890.3025	IPM
Heavy Duty B/K Suspension Sleeve, Size 1	1310	890.3025	IPM
Heavy Duty B/K Suspension Sleeve, Size 2	1311	890.3025	IPM
Heavy Duty B/K Suspension Sleeve, Size 3	1312	890.3025	IPM
Distal Roll-On, Narrow, 2/Bag	1495	890.3025	IPM
Distal Roll-On, Medium, 2/Bag	1496	890.3025	IPM
Distal Roll-On, Wide, 2/Bag	1497	890.3025	IPM
Partial Foot Sock, Regular, 1pc/polybag	10805	890.3025	IPM
Partial Foot Sock, X-Long, 1pc/polybag	10815	890.3025	IPM
Distal End Pad, 1pc/bag	12005	890.3025	IPM
ComfortZone Ultra Cushion Liner, 5 Ply, Size 2, 1pc/bag	12525	890.3025	IPM
ComfortZone Ultra Cushion Liner, 5 Ply, Size 3, 1pc/bag	12535	890.3025	IPM
ComfortZone Ultra Cushion Liner, 3 Ply, Size 1, 1pc/bag	12555	890.3025	IPM
ComfortZone Ultra Cushion Liner, 3 Ply, Size 2, 1pc/bag	12565	890.3025	IPM
ComfortZone Ultra Cushion Liner, 3 Ply, Size 3, 1pc/bag	12575	890.3025	IPM
ComfortZone Double Socket Gel Liner, Short/Narrow	12625	890.3025	IPM
ComfortZone Double Socket Gel Liner, Short/Regular	12655	890.3025	IPM
ComfortZone Double Socket Gel Liner, Medium/Regular	12665	890.3025	IPM
ComfortZone Single Socket Gel Liner, Short/Narrow	12725	890.3025	IPM
ComfortZone Single Socket Gel Liner, Short/Regular	12755	890.3025	IPM
ComfortZone Single Socket Gel Liner, Medium/Regular	12765	890.3025	IPM
Arm Suspension Sleeve	13005	890.3025	IPM
B/K Suspension Sleeve, Size 1	13055	890.3025	IPM

B/K Suspension Sleeve, Size 2	13065	890.3025	IPM
B/K Suspension Sleeve, Size 3	13075	890.3025	IPM
B/K Suspension Sleeve, Size 4	13085	890.3025	IPM
Original BK SiloSheath, Size 1	13315	890.3025	IPM
Original BK SiloSheath, Size 2	13325	890.3025	IPM
Original BK SiloSheath, Size 3	13335	890.3025	IPM
Original BK SiloSheath, Size 4	13345	890.3025	IPM
Original BK SiloSheath, Size 5	13355	890.3025	IPM
Original BK SiloSheath, Size 6	13365	890.3025	IPM
BK SiloSheath, Size 7	13375	890.3025	IPM
BK SiloSheath, Size 8	13385	890.3025	IPM
Double Cushion BK SiloSheath, Size 2	13425	890.3025	IPM
Double Cushion BK SiloSheath, Size 3	13435	890.3025	IPM
Double Cushion BK SiloSheath, Size 4	13445	890.3025	IPM
Double Cushion BK SiloSheath, Size 5	13455	890.3025	IPM
Double Cushion BK SiloSheath, Size 6	13465	890.3025	IPM
Extra Life BK SiloSheath, Size 1	13815	890.3025	IPM
Extra Life BK SiloSheath, Size 2	13825	890.3025	IPM
Extra Life BK SiloSheath, Size 3	13835	890.3025	IPM
Extra Life BK SiloSheath, Size 4	13845	890.3025	IPM
Extra Life BK SiloSheath, Size 5	13855	890.3025	IPM
Extra Life BK SiloSheath, Size 6	13865	890.3025	IPM
Extra Life BK SiloSheath, Size 7	13875	890.3025	IPM
Extra Life BK SiloSheath, Size 8	13885	890.3025	IPM
LA Liner, Cushion, Uniform, 6mm, Medium	18143	890.3025	IPM
Duragel Cushion Liner, Tapered, 6mm, Medium+	18247	890.3025	IPM
Duragel Cushion Liner, Uniform, 9mm, Medium	18261	890.3025	IPM
Antibacterial Silosheath™ - 2 (Short/Narrow): - 1 Per Box	14425	890.3025	IPM
Antibacterial Silosheath™ - 3 (Short/Regular): - 1 Per Box	14435	890.3025	IPM
Antibacterial Silosheath™ - 4 (Medium/Narrow): - 1 Per Box	14445	890.3025	IPM
Antibacterial Silosheath™ - 5 (Medium/Regular): - 1 Per Box	14455	890.3025	IPM
Antibacterial Silosheath™ - 6 (Large/Narrow): - 1 Per Box	14465	890.3025	IPM
Antibacterial Silosheath™ - 7 (Large Regular): - 1 Per Box	14475	890.3025	IPM
Antibacterial Silosheath™ - 8 (Large Wide): - 1 Per Box	14485	890.3025	IPM