



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 880.6450 (FMP)- Protector, Skin Pressure

PRODUCT	ARTICLE NUMBER	CLASSIFICATION	Product Code
Digistrip, Narrow, 2pcs/bag	1100	880.6450	FMP
Digistrip, Medium, 2pcs/bag	1101	880.6450	FMP
Digistrip, Wide, 2pcs/bag	1102	880.6450	FMP
Digital Pads On A Strip, Mini, 2strips/bag	1105	880.6450	FMP
Digital Pads On A Strip, Small/Medium, 2strips/bag	1106	880.6450	FMP
Digital Pads On A Strip, Large/XLarge, 2 strips/bag	1107	880.6450	FMP
Arthritic/Diabetic Gel Sock, Pair, White, 7-9	1701	880.6450	FMP
Arthritic/Diabetic Gel Sock, Pair, White, 9-11	1702	880.6450	FMP
Arthritic/Diabetic Gel Sock, Pair, White, 10-13	1703	880.6450	FMP
Arthritic/Diabetic Gel Sock, Black, 7-9	1706	880.6450	FMP
Arthritic/Diabetic Gel Sock, Black, 9-11	1707	880.6450	FMP
Arthritic/Diabetic Gel Sock, Black, 10-13	1708	880.6450	FMP
Ball Of The Foot Pad, 2pcs/bag	10025	880.6450	FMP
Silopad Digital Pad, Mini, 12pc/bag	10055	880.6450	FMP
Silopad Digital Pad, Small/Medium, 12pc/bag	10065	880.6450	FMP
Silopad Digital Pad, Large/XLarge, 12pcs/bag	10075	880.6450	FMP
Silopad Universal Gel Strap, Pair, Uncovered, Small/Medium	10155	880.6450	FMP
Silopad Universal Gel Strap, Pair, Uncovered, Large/XLarge	10165	880.6450	FMP
Silopad Universal Gel Strap, Pair, Covered, Small/Medium	10175	880.6450	FMP
Silopad Universal Gel Strap, Pair, Covered, Large/XLarge	10185	880.6450	FMP
Silopad Digital Cap, Mini, 6pcs/bag	10195	880.6450	FMP
Silopad Digital Cap, Small/Medium, 6pcs/bag	10205	880.6450	FMP
Silopad Digital Cap, Large/XLarge, 6pcs/bag	10206	880.6450	FMP

Silopad Digital Cap, XXLarge, 6pcs/bag	10207	880.6450	FMP
Silopad Digital Cap, Mesh, 8pcs/bag (1/2" similar to Mini Ribbed Digital Cap, 10195 size)	10235	880.6450	FMP
Silopad Pressure Sensitive Dots, Flat, 1 Sheet (15 dots)	10255	880.6450	FMP
Silopad Gel Foot Cover, Small, 1pair/polybag	10275	880.6450	FMP
Silopad Gel Foot Cover, Medium, 1pair/polybag	10285	880.6450	FMP
Body Disc, 2.5", 2pcs/polybag	10305	880.6450	FMP
Silopad Body Disc, 4" 2pcs/polybag	10315	880.6450	FMP
Gel-E-Roll, 4" x 48", 1roll/box	10355	880.6450	FMP
Silopad Achilles Heel Pad, Small/Medium, 1pc/polybag	10385	880.6450	FMP
Silopad Achilles Heel Pad, Large/XLarge, 1pc/polybag	10395	880.6450	FMP
Metatarsal Pads, 1pair/box	10465	880.6450	FMP
Silopad Softsock, White, Medium, 9-11	10615	880.6450	FMP
Silopad Softsock, White, Large, 10-13	10625	880.6450	FMP
Silopad Mesh Tubing, Wide, 3 x 10", Logo, 1pc/bag	10845	880.6450	FMP
Silopad Mesh Tubing, Narrow, 3pc/polybag	10855	880.6450	FMP
Digi-Tube, Plus, Narrow, 2pcs/bag	10865	880.6450	FMP
Digi-Tube, Plus, Wide, 2pcs/bag	10875	880.6450	FMP
Half Coated Body Sleeve, 3" Width x 3.61 Yards, 1roll/bag	10925	880.6450	FMP
Half Coated Body Sleeve, 4" Width x 3.61" Yards, 1roll/bag	10935	880.6450	FMP
Half Coated Body Sleeve, 5" Width x 3.61 Yards, 1roll/bag	10945	880.6450	FMP
Pressure Relief Padding, 4" x 36", 1pad/cylinder	11205	880.6450	FMP
Pressure Relief Padding, 8" x 36"	11215	880.6450	FMP
Gel Toe Spreader, Small, 4pcs/bag	11505	880.6450	FMP
Gel Toe Spreader, Medium, 4pcs/bag	11515	880.6450	FMP
Gel Toe Spreader, Large, 4pcs/bag	11525	880.6450	FMP
Post Operative Carpal Sleeve, Small, Left	14115	880.6450	FMP
Post Operative Carpal Sleeve, Small Right	14125	880.6450	FMP
Post Operative Carpal Sleeve, Large, Left	14135	880.6450	FMP
Post Operative Carpal Sleeve, Large, Right	14145	880.6450	FMP
Carpal Pads With Pres. Sens.	14205	880.6450	FMP
Malleolar Gel Sleeve	15005	880.6450	FMP
Heel/Elbow Slip Over, Small/Medium	15225	880.6450	FMP
Heel/Elbow Slip Over, Large/XLarge	15235	880.6450	FMP
4" Pressure Sensitive Gel Square, 2 per Sheet	15505	880.6450	FMP
Gel Square, Without Pressure Sensitive Material, 4" x 4"	15515	880.6450	FMP
Soft Shear Gel Sheet, 8" x 8", Fabric on 1 Side	15605	880.6450	FMP
Soft Shear Sheeting, 12"x 16", Fabric on 1 Side	15705	880.6450	FMP
Soft Shear Sheeting, 16"x 20", Fabric on 1 Side	15805	880.6450	FMP

Soft Shear Sheeting, 16"x 20", Fabric on 2 Sides	15815	880.6450	FMP
Skate Bite Protector 1/Pkg	92573	880.6450	FMP
Corn Pads - Narrow - 6 per Polybag	1116	880.6450	FMP
Corn Pads - Medium - 6 per Polybag	1117	880.6450	FMP
Plantar Fasciitis - Left	1140	880.6450	FMP
Plantar Fasciitis - Right	1141	880.6450	FMP