



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 878.4020 (NAD)-Dressing, wound, occlusive

PRODUCT	ARTICLE NUMBER	CLASSIFICATION	Product Code
Gel-Care Advanced Body Wrap, 3"X36"	620	878.4020	NAD
Gel Care, 4"x 4"	760	878.4020	NAD
Gel Care, 5.5"x 8"	761	878.4020	NAD
Gel Care, 1.5"x 10"	762	878.4020	NAD
Silipos Scar Strips	92838	878.4020	NAD