

1) Manufacturer: 3 Point Products, Inc.

Address: 118 Log Canoe Circle
 Stevensville, Maryland, 21666 USA
 Website: www.3pointproducts.com
 Ph. +1 410-604-6393
 SRN: AT-CA-067

On product labels printed as:



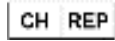
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2) European Authorized Representative:



Sallman Medical GmbH
 Alois-Stockinger
 Straße 16, AT-5020 Salzburg, Austria
 Website: www.sallmann-medical.eu
 eMail: service@sallmann-medical.eu
 SRN: AT-AR-000007881

Swiss Authorized Representative:



Swiss AR Services GmbH
 Industries 47
 CH-6300 Zug

3) Products *(Note: If there are multiple products within one family group, provide list in Table One)*

Product Name: 3pp® Buddy Loops® and 3pp® Toe Loops®; There are multiple product descriptions within this family group. See Table One.

Trade Name: 3pp® Buddy Loops® and 3pp® Toe Loops®

Product Codes: See Table One for Model Numbers

GMDN codes GMDN: 65660; Finger/toe buddy strap, reusable

GMDN Code: 65660; Finger/toe buddy strap

Definition: A flexible preformed device designed to be wrapped around an injured/diseased finger or toe and the adjacent digit to function as a splint-like strap for immobilization of the injured/diseased digit to facilitate healing and/or pain relief. It is made of soft materials and has self-retaining fastening. This is a reusable device.

Intended Purpose: The company specializes in orthoses (also known as splints and braces) for the hand and feet, with a concentration on products designed for persons with arthritis and the resulting deformities caused by inflammatory conditions. All products are designed for ease of use, optimal comfort and for the restoration of hand and foot function. The products are available in a variety of shapes and sizes and may be used for patients in healthcare facilities or at home.

DECLARATION OF CONFORMITY | 3 POINT PRODUCTS, INC.



Basic UDI-DI: See Table One for UPC Codes

Risk Classification: Per MDR Annex VIII, Risk Class: I, rule 1; Non-invasive device intended for short term use ≤ 30 days.

Conformity Procedure: Annex I, II, and III

Relevant CE-Certificate(s): Risk Class I device, self certified

Notified Body: Not Applicable (Risk Class I device)

4) The product(s) described in this DoC are in conformity with:

<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
OJ L117 5.5.2017	Medical Device Regulation (EU-MDR 2017/745)	April 5, 2017

5) Official EU Language(s) English, Dutch, French, German, Spanish, Danish, Swedish, Italian

6) Additional information:

The following harmonized standards have either been referred to or been complied with in part or in full as relevant:

- ISO 13485:2016. Medical devices – Quality management systems – Requirements for regulatory purposes.
- EN 14971:2019 -Medical Devices-Application of Risk Management.
- ISO 15223-1:2021. Medical devices – Symbols to be used with medical devices, labels, labeling, and information to be supplied – Part 1: General requirements.
- EN 1041+A1:2013-Information supplied by the manufacturer of medical devices.

7) Date of first CE marking: February 2002

'I declare that above mentioned medical device complies with the MDR-EU 2017/745 and complies with other relevant EU legislation.'


APPROVAL	
MFG	Julie Belkin
	Owner/President
	Typed or Printed Name
	Title
	May 7, 2022
Signature	Date



TABLE ONE: Declaration of Conformity Product List				
#	SKU	Description	GMDN Code	UPC Code
1	P1003-100	3/4" (1.9 cm) 3pp Buddy Loops 100/ea	65660	847208000087
2	P1003-25	3/4" (1.9 cm) 3pp Buddy Loops 25/ea	65660	847208000094
3	P1003-3	3/4" (1.9 cm) 3pp Buddy Loops 3/ea	65660	847208002203
4	P1003-5	3/4" (1.9 cm) 3pp Buddy Loops 5/ea	65660	847208000100
5	P1003-50	3/4" (1.9 cm) 3pp Buddy Loops 50/ea	65660	847208000117
6	P1005-100	1/2" (1.27 cm) 3pp Buddy Loops 100/ea	65660	847208000155
7	P1005-25	1/2" (1.27 cm) 3pp Buddy Loops 25/ea	65660	847208000162
8	P1005-3	1/2" (1.27 cm) 3pp Buddy Loops 3/ea	65660	874208002210
7	P1005-5	1/2" (1.27 cm) 3pp Buddy Loops 5/ea	65660	847208000179
9	P1005-50	1/2" (1.27 cm) 3pp Buddy Loops 50/ea	65660	847208000148
10	P1007-100	1" (2.5 cm) 3pp Buddy Loops 100/ea	65660	847208000209
11	P1007-25	1" (2.5 cm) 3pp Buddy Loops 25/ea	65660	847208000216
12	P1007-5	1" (2.5 cm) 3pp Buddy Loops 5/ea	65660	847208000223
13	P1007-50	1" (2.5 cm) 3pp Buddy Loops 50/ea	65660	847208000230
14	P5001-25	3pp Toe Loops Narrow 25/ea	65660	847208001671
15	P5001-25	3pp Toe Loops Narrow 3/ea	65660	847208001893
16	P5001-5	3pp Toe Loops Narrow 5/ea	65660	847208001688
17	P5002-25	3pp Toe Loops Wide 25/ea	65660	847208001695
18	P5002-3	3pp Toe Loops Wide 3/ea	65660	847208001909
19	P5002-5	3pp Toe Loops Wide 5/ea	65660	847208001701