

DECLARATION OF CONFORMITY | 3 POINT PRODUCTS, INC.



1) Manufacturer: 3 Point Products, Inc.
Address:

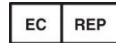
118 Log Canoe Circle
Stevensville, Maryland, 21666 USA
Website: www.3pointproducts.com
Ph. +1 410-604-6393
SRN: AT-CA-067

On product labels
printed as:



3 Point Products, Inc.
118 Log Canoe Circle
Stevensville, Maryland, 21666 USA
Website: www.3pointproducts.com
Ph. +1 410-604-6393

2) European
Authorized
Representative:



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

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

Product Name: Oval-8 Finger Splints; There are multiple product descriptions within the family group of Oval-8 Finger Splints. See Table One.

Trade Names: Oval-8 Finger Splints

Product Codes: See Table One for Oval-8 Model Numbers

GMDN Code: GMDN: 42874; Hand/finger splint, reusable

GMDN
Definition: A rigid or semi-rigid device intended to immobilize an injured, diseased hand and/or finger to support, align or prevent injury during the healing process. It is applied externally to the hand, finger, wrist and typically held in place with self-retaining fasteners (e.g., Velcro bands) or bandage wraps. This is a reusable device.

Intended
Purpose: A nonsterile, non-invasive device intended to stabilize and align the Proximal Interphalangeal Joint (PIP Joint) or Distal Interphalangeal Joint (DIP Joint) of a finger. It is intended to be used for tendon or ligament injuries, to protect healing fractures, support unstable joints and prevent contractures. More specifically the devices are used in the treatment of the following clinical conditions: 1) Trigger Finger, 2)

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Swan Neck Deformity, 3) Boutonniere Deformity, 4) Lateral Deviation, 5) Mallet Finger, and 6) Finger Fracture.

Basic UDI-DI: See Table One for 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 (General Safety and Performance Requirements), Annex II (Technical Documentation), and Annex III (Post-market Surveillance)

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.
- ISO 20417:2021-Information supplied by the manufacturer of medical devices.

7) Date of first CE marking: February 2002

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'I declare that the mentioned medical devices comply with the MDR-EU 2017/745 and comply with other relevant EU legislation.'


APPROVAL		
MFG	Julie Belkin	President/CEO
	Typed or Printed Name	Title
		2022-08-24
	Signature	Date

TABLE ONE: Declaration of Conformity Product List				
#	SKU	Description	GMDN Code	Basic UDI-DI Code
1	P1008-CB1	Oval-8 Combo sizes. 2, 3, 4, 5, 6 (1/ea)	42874	847208003859
2	P1008-CB2	Oval-8 Combo sizes 5, 6, 7, 8, 9 (1/ea)	42874	847208003866
3	P1008-CB3	Oval-8 Combo sizes 8, 9, 10, 11, 12 (1/ea)	42874	847208003873
4	P1008-CB4	Oval-8 Combo sizes 11, 12, 13, 14, 15 (1/ea)	42874	847208003880
5	P1008-1-02	Oval-8 Size 2 (1/ea)	42874	847208000360
6	P1008-1-03	Oval-8 Size 3 (1/ea)	42874	847208000384
7	P1008-1-04	Oval-8 Size 4 (1/ea)	42874	847208000407
8	P1008-1-05	Oval-8 Size 5 (1/ea)	42874	847208000421
9	P1008-1-06	Oval-8 Size 6 (1/ea)	42874	847208000445
10	P1008-1-07	Oval-8 Size 7 (1/ea)	42874	847208000469
11	P1008-1-08	Oval-8 Size 8 (1/ea)	42874	847208000483
12	P1008-1-09	Oval-8 Size 9 (1/ea)	42874	847208000506
13	P1008-1-10	Oval-8 Size 10 (1/ea)	42874	847208000247
14	P1008-1-11	Oval-8 Size 11 (1/ea)	42874	847208000261
15	P1008-1-12	Oval-8 Size 12 (1/ea)	42874	847208000285
16	P1008-1-13	Oval-8 Size 13 (1/ea)	42874	847208000308
17	P1008-1-14	Oval-8 Size 14 (1/ea)	42874	847208000322
18	P1008-1-15	Oval-8 Size 15 (1/ea)	42874	847208000346
19	P1008-3-02	Oval-8 Size 2 (3/ea)	42874	847208000356
20	P1008-3-03	Oval-8 Size 3 (3/ea)	42874	847208000357
21	P1008-3-04	Oval-8 Size 4 (3/ea)	42874	847208000358
22	P1008-3-05	Oval-8 Size 5 (3/ea)	42874	847208000359
23	P1008-3-06	Oval-8 Size 6 (3/ea)	42874	847208000360
24	P1008-3-07	Oval-8 Size 7 (3/ea)	42874	847208000361
25	P1008-3-08	Oval-8 Size 8 (3/ea)	42874	847208000362
26	P1008-3-09	Oval-8 Size 9 (3/ea)	42874	847208000363
27	P1008-3-10	Oval-8 Size 10 (3/ea)	42874	847208000364
28	P1008-3-11	Oval-8 Size 11 (3/ea)	42874	847208000365



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#	SKU	Description	GMDN Code	Basic UDI-DI Code
29	P1008-3-12	Oval-8 Size 12 (3/ea)	42874	847208000366
30	P1008-3-13	Oval-8 Size 13 (3/ea)	42874	847208000367
31	P1008-3-14	Oval-8 Size 14 (3/ea)	42874	847208000368
32	P1008-3-15	Oval-8 Size 15 (3/ea)	42874	847208000369
33	P1008-5-02	Oval-8 Size 2 (5/ea)	42874	847208000377
34	P1008-5-03	Oval-8 Size 3 (5/ea)	42874	847208000391
35	P1008-5-04	Oval-8 Size 4 (5/ea)	42874	847208000414
36	P1008-5-05	Oval-8 Size 5 (5/ea)	42874	847208000438
37	P1008-5-06	Oval-8 Size 6 (5/ea)	42874	847208000452
38	P1008-5-07	Oval-8 Size 7 (5/ea)	42874	847208000476
39	P1008-5-08	Oval-8 Size 8 (5/ea)	42874	847208000490
40	P1008-5-09	Oval-8 Size 9 (5/ea)	42874	847208000513
41	P1008-5-10	Oval-8 Size 10 (5/ea)	42874	847208000254
42	P1008-5-11	Oval-8 Size 11 (5/ea)	42874	847208000278
43	P1008-5-12	Oval-8 Size 12 (5/ea)	42874	847208000292
44	P1008-5-13	Oval-8 Size 13 (5/ea)	42874	847208000315
45	P1008-5-14	Oval-8 Size 14 (5/ea)	42874	847208000339
46	P1008-5-15	Oval-8 Size 15 (5/ea)	42874	847208000353
47	RP1008-001	Oval-8 Graduated Set Sizes 2,3,4 (1/ ea)	42874	847208002234
48	RP1008-002	Oval-8 Graduated Set Sizes 4,5,6 (1/ ea)	42874	847208002241
49	RP1008-003	Oval-8 Graduated Set Sizes 6,7,8 (1/ ea)	42874	847208002258
50	RP1008-004	Oval-8 Graduated Set Sizes 8,9,10 (1/ ea)	42874	847208002265
51	RP1008-005	Oval-8 Graduated Set Sizes 10,11,12 (1/ ea)	42874	847208002272
52	RP1008-006	Oval-8 Graduated Set Sizes 13,14,15 (1/ ea)	42874	847208002289
53	P1008-K	Oval-8 Kit Sizes 2-15 (44 /Pkg)	42874	847208000520
54	P1008-PK	Oval-8 Pediatric Kit Sizes 3-7 (3/ea)	42874	847208000025
55	P1008-S	Oval-8 Sizing Set Sizes 2-15 (1/ea)	42874	847208000018



Declaration of Conformity Revision History		
Revision Number	Prepared by	Description of revision
00	Laura Kasperowicz (QNET)	New release in updated format in order to comply with the EU Medical Device Regulation (EU-MDR 2017/745). Change Authorized Representative from Emergo Europe (Netherlands) to Sallmann Medical (Austria).
01	Laura Kasperowicz (QNET)	In section 6, ISO 15223-1-2016 has been updated to the most recent standard, ISO 15223-1-2021.
02	Laura Kasperowicz (QNET)	Updated standard in Section 6 from EN 1041:A1:2013 to ISO 20417:2021. Updated Table One to replace the UPC Codes to GS1 UDI-DI Codes.