



118 Log Canoe Circle  
Stevensville, MD 21666, USA

Tel: ++1-410-604-6393; Fax ++1-410-604-6398

# Declaration of Conformity

| PRODUCT IDENTIFICATION |               |
|------------------------|---------------|
| Product name           | Model/number  |
| Oval-8®                | See next page |

| MANUFACTURER           |   |                |
|------------------------|---|----------------|
| Name of company        | Address   | Representative |
| 3-Point Products, Inc. | 118 Log Canoe Circle<br>Stevensville, MD 21666, USA | Julie Belkin   |

| AUTHORIZED REPRESENTATIVE |  |   |
|---------------------------|--|---|
| Name of company           | Address  | Telephone/email   |
| Emergo Europe             | Prinsessegracht 20<br>2514 AP<br>The Hague Netherlands | +31.70.345.8570 - phone<br>+31.70.346.7299 - fax<br>service@emergogroup.com |

| CONFORMITY ASSESSMENT            |  |                   |
|----------------------------------|--|-------------------|
| Device classification            | Route to compliance  | Standards applied |
| Class 1 self-certified<br>Rule 1 | Annex VII of MDD<br>93/42/EEC Council<br>Directive as amended by<br>2007/47/EC | Optional          |

**3-Point Products, Inc.** declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Julie Belkin

**TITLE:** President

**SIGNATURE:**

**DATE:** 6 February 2017



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## Declaration of Conformity – Page 2

### Oval-8 Finger Splints

| Model #    | Description             |            |  |
|------------|-------------------------|------------|--|
| P1008-1-02 | Oval-8 Pkg of 1 Size 2  | P1008-GS1  | Oval-8 Graduated Set Bag of 2, 3, 4    |
| P1008-1-03 | Oval-8 Pkg of 1 Size 3  | P1008-GS2  | Oval-8 Graduated Set Bag of 4, 5, 6    |
| P1008-1-04 | Oval-8 Pkg of 1 Size 4  | P1008-GS3  | Oval-8 Graduated Set Bag of 6, 7, 8    |
| P1008-1-05 | Oval-8 Pkg of 1 Size 5  | P1008-GS4  | Oval-8 Graduated Set Bag of 8, 9, 10   |
| P1008-1-06 | Oval-8 Pkg of 1 Size 6  | P1008-GS5  | Oval-8 Graduated Set Bag of 10, 11, 12 |
| P1008-1-07 | Oval-8 Pkg of 1 Size 7  | P1008-GS6  | Oval-8 Graduated Set Bag of 13, 14, 15 |
| P1008-1-08 | Oval-8 Pkg of 1 Size 8  |            |  |
| P1008-1-09 | Oval-8 Pkg of 1 Size 9  | RP1008-001 | Oval-8 Graduated Set Sizes 2, 3, 4     |
| P1008-1-10 | Oval-8 Pkg of 1 Size 10 | RP1008-002 | Oval-8 Graduated Set Sizes 4, 5, 6     |
| P1008-1-11 | Oval-8 Pkg of 1 Size 11 | RP1008-003 | Oval-8 Graduated Set Sizes 6, 7, 8     |
| P1008-1-12 | Oval-8 Pkg of 1 Size 12 | RP1008-004 | Oval-8 Graduated Set Sizes 8, 9, 10    |
| P1008-1-13 | Oval-8 Pkg of 1 Size 13 | RP1008-005 | Oval-8 Graduated Set Sizes 10, 11, 12  |
| P1008-1-14 | Oval-8 Pkg of 1 Size 14 | RP1008-006 | Oval-8 Graduated Set Sizes 13, 14, 15  |
| P1008-1-15 | Oval-8 Pkg of 1 Size 15 |            |  |
|            |                         |            |  |
| P1008-3-02 | Oval-8 Pkg of 3 Size 2  | P1008-C1   | Oval-8 Combo sizes 3, 4, 5, 6, 7       |
| P1008-3-03 | Oval-8 Pkg of 3 Size 3  | P1008-C2   | Oval-8 Combo sizes 6, 7, 8, 9, 10      |
| P1008-3-04 | Oval-8 Pkg of 3 Size 4  | P1008-C3   | Oval-8 Combo sizes 10, 11, 12, 13, 14  |
| P1008-3-05 | Oval-8 Pkg of 3 Size 5  |            |  |
| P1008-3-06 | Oval-8 Pkg of 3 Size 6  | P1008-K    | Oval-8 Kit                             |
| P1008-3-07 | Oval-8 Pkg of 3 Size 7  | P1008-PK   | Oval-8 Pediatric Kit                   |
| P1008-3-08 | Oval-8 Pkg of 3 Size 8  | P1008-S    | Oval-8 Sizing Set                      |
| P1008-3-09 | Oval-8 Pkg of 3 Size 9  |            |  |
| P1008-3-10 | Oval-8 Pkg of 3 size 10 |            |  |
| P1008-3-11 | Oval-8 Pkg of 3 size 11 |            |  |
| P1008-3-12 | Oval-8 Pkg of 3 size 12 |            |  |
| P1008-3-13 | Oval-8 Pkg of 3 size 13 |            |  |
| P1008-3-14 | Oval-8 Pkg of 3 size 14 |            |  |
| P1008-3-15 | Oval-8 Pkg of 3 size 15 |            |  |
|            |                         |            |  |
| P1008-5-02 | Oval-8 Pkg of 5 Size 2  |            |  |
| P1008-5-03 | Oval-8 Pkg of 5 Size 3  |            |  |
| P1008-5-04 | Oval-8 Pkg of 5 Size 4  |            |  |
| P1008-5-05 | Oval-8 Pkg of 5 Size 5  |            |  |
| P1008-5-06 | Oval-8 Pkg of 5 Size 6  |            |  |
| P1008-5-07 | Oval-8 Pkg of 5 Size 7  |            |  |
| P1008-5-08 | Oval-8 Pkg of 5 Size 8  |            |  |
| P1008-5-09 | Oval-8 Pkg of 5 Size 9  |            |  |
| P1008-5-10 | Oval-8 Pkg of 5 size 10 |            |  |
| P1008-5-11 | Oval-8 Pkg of 5 size 11 |            |  |
| P1008-5-12 | Oval-8 Pkg of 5 size 12 |            |  |
| P1008-5-13 | Oval-8 Pkg of 5 size 13 |            |  |
| P1008-5-14 | Oval-8 Pkg of 5 size 14 |            |  |
| P1008-5-15 | Oval-8 Pkg of 5 size 15 |            |  |