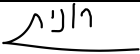




### Written or Updated by:

Name	Title	Date	Signature
Ronit Sadeh	QA/RA Consultant	24 March 2020	

### Reviewed by:

Name	Title	Date	Signature
Tamar Ish Cassit	CEO	24-March-2020	

### Approved by:

Name	Title	Date	Signature
Tamar Ish Cassit	CEO	24-March-2020	

### Revision History:

Rev. no.	Written by:	Description of Change	Date Signed
01	Assaf Gur	First issue.	8-Jan-2020
02	Assaf Gur	Splint Name Changing	23-Jan-2020
03	Ronit Sadeh	Addition of OTC and preparatory kit	23- March - 2020

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# EC DECLARATION OF CONFORMITY



**European Medical Device Directive 93/42 EEC'  
as amended by Council Directive 2007/47/EC (MDD)**

Manufacturer	<b>Cassit Orthopedics Ltd. Elifelet 26, Tel Aviv - Israel 6608026</b>
EU Notify Body	<b>N.A.</b>
EC Authorized representative	<b>MedNet GmbH Borkstrasse 10 48163 Muenster Germany</b>

We the undersigned hereby declare that the distributed CE marked products, specified below, that are placed in the European market, meet the provisions of the Medical Device Directive 93/42 EEC as amended by Council Directive 2007/47/EC (MDD), and all applicable Essential Requirements set out in Annex I of the MDD.

In addition, we ensure and declare that the distributed CE marked products, classified as Class I under Rule 1 of Annex IX according to MEDDEV 2.4/1 Rev. 9 – Classification of medical devices, conforms to the essential requirements listed in Annex I of the EC Directive 93/42/EEC.

This declaration is supported by the establishment of a Quality System based on the harmonized standard EN ISO 13485:2016.

The Declaration of Conformity is valid unless otherwise is stated.

**Product List**

<b>Product Description</b>	<b>Class</b>	<b>Catalog Number</b>
<b>Cassit Splint</b>		
Functional Splint Adult Light Kit	I	10015-G/E/N/Y/P/B/R
Functional Splint Adult Strong Kit	I	10017-G/E/N/Y/P/B/R
Functional Splint Little Child Kit	I	10011-G/E/N/Y/P/B/R
Functional Splint Big Child Kit	I	10012-G/E/N/Y/P/B/R
Rest Splint Adult Kit	I	10005-G/E/N/Y/P/B/R
Rest Splint Teen Kit	I	10003-G/E/N/Y/P/B/R
Rest Splint Child Kit	I	10002-G/E/N/Y/P/B/R
Ulnar Functional Splint Teen Kit	I	10023-G/E/N/Y/P/B/R
Ulnar Functional Splint Adult Kit	I	10025-G/E/N/Y/P/B/R
Functional Thumb Splint Adult Kit	I	10049-G/E/N/Y/P/B/R
Wide Finger Splint 1 Kit	I	10041-G/E/N/Y/P/B/R
Narrow Finger Splint 1 Kit	I	10031-G/E/N/Y/P/B/R
Wide Finger Splint 2 Kit	I	10042-G/E/N/Y/P/B/R
Narrow Finger Splint 2 Kit	I	10032-G/E/N/Y/P/B/R
Wide Finger Splint 3 Kit	I	10043-G/E/N/Y/P/B/R
Narrow Finger Splint 3 Kit	I	10033-G/E/N/Y/P/B/R
Narrow Finger 4 Kit	I	10034-G/E/N/Y/P/B/R
Short Arm Fracture Splint Adult Kit	I	10105-G/E/N/Y/P/B/R
Short Arm Fracture Splint Teen Kit	I	10103-G/E/N/Y/P/B/R
Wide Peripheral Strap Set	I	12601-G/E/N/Y/P/B/R
Rest Splint Child Right	I	12002-G/E/N/Y/P/B/R
Rest Splint Child Left	I	13002-G/E/N/Y/P/B/R
Rest Splint Teen Right	I	12003-G/E/N/Y/P/B/R
Rest Splint Teen Left	I	13003-G/E/N/Y/P/B/R
Rest Splint Adult Right	I	12005-G/E/N/Y/P/B/R
Rest Splint Adult Left	I	13005-G/E/N/Y/P/B/R

Functional Splint Little Child Right	I	12011-G/E/N/Y/P/B/R
Functional Splint Little Child Left	I	13011-G/E/N/Y/P/B/R
Functional Splint Big Child Right	I	12012-G/E/N/Y/P/B/R
Functional Splint Big Child Left	I	13012-G/E/N/Y/P/B/R
Functional Splint Adult Light Right	I	12015-G/E/N/Y/P/B/R
Functional Splint Adult Light Left	I	13015-G/E/N/Y/P/B/R
Functional Splint Adult Strong Right	I	12017-G/E/N/Y/P/B/R
Functional Splint Adult Strong Left	I	13017-G/E/N/Y/P/B/R
Ulnar Functional Splint Teen Right	I	12023-G/E/N/Y/P/B/R
Ulnar Functional Splint Teen Left	I	13023-G/E/N/Y/P/B/R
Ulnar Functional Splint Adult Right	I	12025-G/E/N/Y/P/B/R
Ulnar Functional Splint Adult Left	I	13025-G/E/N/Y/P/B/R
Functional Thumb Splint Adult Right	I	12049-G/E/N/Y/P/B/R
Functional Thumb Splint Adult Left	I	13049-G/E/N/Y/P/B/R
Short Arm Fracture Splint Teen Right	I	12103-G/E/N/Y/P/B/R
Short Arm Fracture Splint Teen Left	I	13103-G/E/N/Y/P/B/R
Short Arm Fracture Splint Adult Right	I	12105-G/E/N/Y/P/B/R
Short Arm Fracture Splint Adult Left	I	13105-G/E/N/Y/P/B/R
Narrow Finger Splint 1, Single	I	12031-G/E/N/Y/P/B/R
Wide Finger Splint 1, Single	I	12041-G/E/N/Y/P/B/R
Narrow Finger Splint 2, Single	I	12032-G/E/N/Y/P/B/R
Wide Finger Splint 2, Single	I	12042-G/E/N/Y/P/B/R
Narrow Finger Splint 3, Single	I	12033-G/E/N/Y/P/B/R
Wide Finger Splint 3, Single	I	12043-G/E/N/Y/P/B/R
Narrow Finger Splint 4, Single	I	12034-G/E/N/Y/P/B/R
Functional Adult Strap Set	I	50015-G/E/N/Y/P/B/R
Functional Little Child Strap Set	I	50011-G/E/N/Y/P/B/R
Functional Big Child Strap Set	I	50012-G/E/N/Y/P/B/R
Rest Adult Strap Set	I	50005-G/E/N/Y/P/B/R
Rest Teen Strap Set	I	50003-G/E/N/Y/P/B/R
Rest Child Strap Set	I	50002-G/E/N/Y/P/B/R
Ulnar Functional Teen Strap Set	I	50023-G/E/N/Y/P/B/R
Ulnar Functional Adult Strap Set	I	50025-G/E/N/Y/P/B/R

Functional Thumb Adult Strap Set	I	50049-G/E/N/Y/P/B/R
Wide Finger Strap Set	I	50040-G/E/N/Y/P/B/R
Narrow Finger Strap Set	I	50030-G/E/N/Y/P/B/R
Short Arm Fracture Adult Strap Set	I	50105-G/E/N/Y/P/B/R
Short Arm Fracture Teen Strap Set	I	50103-G/E/N/Y/P/B/R
Fork Holder Child Right	I	12066-G/E/N/Y/P/B/R
Fork Holder Child Left	I	13066-G/E/N/Y/P/B/R
Fork Holder Adult Right	I	12068-G/E/N/Y/P/B/R
Fork Holder Adult Left	I	13068-G/E/N/Y/P/B/R
Sponge Tube Child	I	12071-G/E/N/Y/P/B/R
Sponge Tube Adult	I	12073-G/E/N/Y/P/B/R
Writing Loop S Kit	I	12501-G/E/N/Y/P/B/R
Writing Loop M Kit	I	12503-G/E/N/Y/P/B/R
Writing Loop L Kit	I	12505-G/E/N/Y/P/B/R
Pair of Heat Gloves Large	I	10705-G/E/N/Y/P/B/R
Pair of Heat Gloves Medium	I	12703-G/E/N/Y/P/B/R
Cassit Towel	I	12801
Cassit water bath Small	I	60001
Cassit water bath Medium	I	60002
Cassit water bath Large	I	60003
Tongs Small	I	60011
Tongs Medium	I	60013
Tongs Large	I	60015

- All kits may contain preparatory kit which includes: Gloves, bath, Fork Holder, Sponge Tube & Writing Loop.
- R= Red, B = Blue, P = Pink, Y= Yellow, N= Orange, E=Light Gray, G = Green. No letter = Dark Gray.

Name: Tamar Ish Cassit

Title: CEO

Date: 24-March-2020

Signature:

