




Written or Updated by:

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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
04	Ronit Sadeh	Addition of Packs, change in colors and CN	13- April -2021
05	Ronit Sadeh	Update according MDR	01/08/21

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EC DECLARATION OF CONFORMITY



Regulation MDR 2017/745

Manufacturer

Cassit Orthopedics Ltd.

EU Notify Body

Eliphelet 26, Tel Aviv - Israel 6608026

EC Authorized representative

N.A.**MedNet GmbH Borkstrasse 10 48163****Muenster Germany**

This declaration of conformity is issued under the sole responsibility of [MANUFACTURER]. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

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

All supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is valid unless otherwise is stated.

Product List

Product Description	Class	Catalog Number (CN)
Cassit Splint		
Functional Splint Adult Light Kit	I	10015-G/E/N/Y/P/B/R/K/W/V
Functional Splint Adult Strong Kit	I	10017-G/E/N/Y/P/B/R/K/W/V
Functional Splint Child S Kit	I	10011-G/E/N/Y/P/B/R/K/W/V
Functional Splint Child L Kit	I	10012-G/E/N/Y/P/B/R/K/W/V
Rest Splint Adult Kit	I	10005-G/E/N/Y/P/B/R/K/W/V
Rest Splint Teen Kit	I	10003-G/E/N/Y/P/B/R/K/W/V
Rest Splint Child Kit	I	10002-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Child Kit	I	10022-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Teen Kit	I	10023-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Adult Kit	I	10025-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint Adult Kit	I	10049-G/E/N/Y/P/B/R/K/W/V
Wide Finger Splint XL Kit	I	10041-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Splint XL Kit	I	10031-G/E/N/Y/P/B/R/K/W/V
Wide Finger Splint Large Kit	I	10042-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Splint Large Kit	I	10032-G/E/N/Y/P/B/R/K/W/V
Wide Finger Splint Medium Kit	I	10043-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Splint Medium Kit	I	10033-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Small Kit	I	10034-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint Adult Kit	I	10105-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint Teen Kit	I	10103-G/E/N/Y/P/B/R/K/W/V
Wide Peripheral Strap Set	I	10601-G/E/N/Y/P/B/R/K/W/V
Rest Splint Child 5-Pack	I	91002-G/E/N/Y/P/B/R/K/W/V
Rest Splint Teen 5-Pack	I	91003-G/E/N/Y/P/B/R/K/W/V
Rest Splint Adult 5-Pack	I	91005-G/E/N/Y/P/B/R/K/W/V

Functional Splint Child S 5-Pack	I	91011-G/E/N/Y/P/B/R/K/W/V
Functional Splint Child M 5-Pack	I	91012-G/E/N/Y/P/B/R/K/W/V
Functional Splint Adult Light 5-Pack	I	91015-G/E/N/Y/P/B/R/K/W/V
Functional Splint Adult Strong 5-Pack	I	91017-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Child 5-Pack	I	91022-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Teen 5-Pack	I	91023-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Adult 5-Pack	I	91025-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint Adult 5-Pack	I	91049-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Splint XL 5-Pack	I	91031-G/E/N/Y/P/B/R/K/W/V
Wide Finger Splint XL 5-Pack	I	91041-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Splint L 5-Pack	I	91032-G/E/N/Y/P/B/R/K/W/V
Wide Finger Splint L 5-Pack	I	91042-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Splint M 5-Pack	I	91033-G/E/N/Y/P/B/R/K/W/V
Wide Finger Splint M 5-Pack	I	91043-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Splint S 5-Pack	I	91034-G/E/N/Y/P/B/R/K/W/V
Fork Holder Child 10-Pack	I	91066-G/E/N/Y/P/B/R/K/W/V
Fork Holder Adult 10-Pack	I	91068-G/E/N/Y/P/B/R/K/W/V
Sponge Tube Child 10-Pack	I	91071-G/E/N/Y/P/B/R/K/W/V
Sponge Tube Adult 10-Pack	I	91073-G/E/N/Y/P/B/R/K/W/V
Writing Loop S 10-Pack	I	91501-G/E/N/Y/P/B/R/K/W/V
Writing Loop M 10-Pack	I	91503-G/E/N/Y/P/B/R/K/W/V
Writing Loop L 10-Pack	I	91505-G/E/N/Y/P/B/R/K/W/V
Rest Splint (Child) S Right	I	12002-G/E/N/Y/P/B/R/K/W/V
Rest Splint (Child) S Left	I	13002-G/E/N/Y/P/B/R/K/W/V
Rest Splint (Teen) M Right	I	12003-G/E/N/Y/P/B/R/K/W/V
Rest Splint (Teen) M Left	I	13003-G/E/N/Y/P/B/R/K/W/V
Rest Splint (Adult) L Right	I	12005-G/E/N/Y/P/B/R/K/W/V
Rest Splint (Adult) L Left	I	13005-G/E/N/Y/P/B/R/K/W/V

Functional Splint (Child) S Right	I	12011-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Child) S Left	I	13011-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Child) MS Right	I	12012-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Child) MS Left	I	13012-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Light) M Right	I	12014-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Light) L Right	I	12015-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Light) M Left	I	13014-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Light) L Left	I	13015-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Strong) XL Right	I	12017-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Strong) XL Left	I	13017-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Teen) S Right	I	12023-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Teen) M Right	I	12024-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Teen) S Left	I	13023-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Teen) M Left	I	13024-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Adult) L Right	I	12025-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Adult) XL Right	I	12026-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Adult) L Left	I	13025-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Adult) XL Left	I	13026-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint (Adult) M Right	I	12047-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint (Adult) L Right	I	12048-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint (Adult) XL Right	I	12049-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint (Adult) M Left	I	13047-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint (Adult) L Left	I	13048-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint (Adult) XL Left	I	13049-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint (Teen) M Right	I	12103-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint (Teen) M Left	I	13103-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint (Adult) L Right	I	12105-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint (Adult) L Left	I	13105-G/E/N/Y/P/B/R/K/W/V

Short Arm Fracture Splint (Adult) XL Right	I	12106-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint (Adult) XL Left	I	13106-G/E/N/Y/P/B/R/K/W/V
Finger Splint (1W) XL, Single	I	12041-G/E/N/Y/P/B/R/K/W/V
Finger Splint (2W) L, Single	I	12042-G/E/N/Y/P/B/R/K/W/V
Finger Splint (2N) M, Single	I	12032-G/E/N/Y/P/B/R/K/W/V
Wide Finger Splint MS (Medium-Small) (3W), Single	I	12043-G/E/N/Y/P/B/R/K/W/V
Finger Splint S (3N), Single	I	12033-G/E/N/Y/P/B/R/K/W/V
Finger Splint XS (4N), Single	I	12034-G/E/N/Y/P/B/R/K/W/V
Fork Holder (Child) S Left	I	13066-G/E/N/Y/P/B/R/K/W/V
Fork Holder (Child) S Right	I	12066-G/E/N/Y/P/B/R/K/W/V
Fork Holder (Adult) M Left	I	13068-G/E/N/Y/P/B/R/K/W/V
Fork Holder (Adult) M Right	I	12068-G/E/N/Y/P/B/R/K/W/V
Fork Holder (Adult) L Left	I	13069-G/E/N/Y/P/B/R/K/W/V
Fork Holder (Adult) L Right	I	12069-G/E/N/Y/P/B/R/K/W/V
Sponge Tube (Child) S	I	12071-G/E/N/Y/P/B/R/K/W/V
Sponge Tube (Adult) L	I	12073-G/E/N/Y/P/B/R/K/W/V
Writing Loop S, Single	I	12501-G/E/N/Y/P/B/R/K/W/V
Writing Loop M, Single	I	12503-G/E/N/Y/P/B/R/K/W/V
Writing Loop L, Single	I	12505-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Child) S STRAP SET	I	58011-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Child) MS STRAP SET	I	58012-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Light) M STRAP SET	I	58014-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Light) L STRAP SET	I	58015-G/E/N/Y/P/B/R/K/W/V
Functional Splint (Adult Strong) XL STRAP SET	I	58017-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Teen) S STRAP SET	I	58023-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Teen) M STRAP SET	I	58024-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Adult) L STRAP SET	I	58025-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint (Adult) XL STRAP SET	I	58026-G/E/N/Y/P/B/R/K/W/V

Finger Strap Set L/ XL	I	58040-G/E/N/Y/P/B/R/K/W/V
Finger Strap Set M/ S	I	58030-G/E/N/Y/P/B/R/K/W/V
Rest L Strap Set	I	58005-G/E/N/Y/P/B/R/K/W/V
Rest M Strap Set	I	58003-G/E/N/Y/P/B/R/K/W/V
Rest S Strap Set	I	58002-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint M	I	58103-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Splint L	I	58105-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Strap Set M	I	58047-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Strap Set L	I	58048-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Strap Set XL	I	58049-G/E/N/Y/P/B/R/K/W/V
Functional Adult Strap Set	I	50015-G/E/N/Y/P/B/R/K/W/V
Functional Child S Strap Set	I	50011-G/E/N/Y/P/B/R/K/W/V
Functional Child L Strap Set	I	50012-G/E/N/Y/P/B/R/K/W/V
Rest Adult Strap Set	I	50005-G/E/N/Y/P/B/R/K/W/V
Rest Teen Strap Set	I	50003-G/E/N/Y/P/B/R/K/W/V
Rest Child Strap Set	I	50002-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Teen Strap Set	I	50023-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Adult Strap Set	I	50025-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Adult Strap Set	I	50049-G/E/N/Y/P/B/R/K/W/V
Wide Finger Strap Set	I	50040-G/E/N/Y/P/B/R/K/W/V
Narrow Finger Strap Set	I	50030-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Adult Strap Set	I	50105-G/E/N/Y/P/B/R/K/W/V
Short Arm Fracture Teen Strap Set	I	50103-G/E/N/Y/P/B/R/K/W/V
Extra Straps – Mix 1	I	56001-G/E/N/Y/P/B/R/K/W/V
Rest Splint Strap Set Child 5 Pack	I	96002-G/E/N/Y/P/B/R/K/W/V
Rest Splint Strap Set Teen 5 Pack	I	96003-G/E/N/Y/P/B/R/K/W/V
Rest Splint Strap Set Adult 5 Pack	I	96005-G/E/N/Y/P/B/R/K/W/V
Functional Splint Straps Set Child Small 5 Pack	I	96011-G/E/N/Y/P/B/R/K/W/V

Functional Splint Straps Set Child Medium 5 Pack	I	96012-G/E/N/Y/P/B/R/K/W/V
Functional Splint Strap Set Adult 5 Pack	I	96015-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Strap Set Child 5 Pack	I	96022-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Strap Set Teen 5 Pack	I	96023-G/E/N/Y/P/B/R/K/W/V
Ulnar Functional Splint Strap Set Adult 5 Pack	I	96025-G/E/N/Y/P/B/R/K/W/V
Functional Thumb Splint Strap Set Adult 5 Pack	I	96049-G/E/N/Y/P/B/R/K/W/V
Finger Splint Strap Set Narrow 10 Pack	I	96030-G/E/N/Y/P/B/R/K/W/V
Finger Splint Strap Set Wide 10 Pack	I	96040-G/E/N/Y/P/B/R/K/W/V
Closer 64 Extra Straps 50 Pack	I	84103-G/E/N/Y/P/B/R/K/W/V
Strap 90 Extra Straps 50 Pack	I	84105-G/E/N/Y/P/B/R/K/W/V
Strap 110 Extra Straps 25 Pack	I	84160-G/E/N/Y/P/B/R/K/W/V
Strap 130 Extra Straps 25 Pack	I	84107-G/E/N/Y/P/B/R/K/W/V
Strap 155 Extra Straps 25 Pack	I	84109-G/E/N/Y/P/B/R/K/W/V
Strap 180 Extra Straps 20 Pack	I	84111-G/E/N/Y/P/B/R/K/W/V
Strap 220 Extra Straps 25 Pack	I	84113-G/E/N/Y/P/B/R/K/W/V
Finger Strap 65 Extra Straps 50 Pack	I	84137-G/E/N/Y/P/B/R/K/W/V
Finger Strap 80 Extra Straps 50 Pack	I	84139-G/E/N/Y/P/B/R/K/W/V
Finger Strap 100 Extra Straps 50 Pack	I	84141-G/E/N/Y/P/B/R/K/W/V
Peripheral Strap 160 Extra Straps 25 Pack	I	84125-G/E/N/Y/P/B/R/K/W/V
Wide Peripheral Straps #180 Extra Straps 10 Pack	I	84601-G/E/N/Y/P/B/R/K/W/V
Extra Straps Mix Set 1, 5 Pack	I	84561-G/E/N/Y/P/B/R/K/W/V
Fork Holder Child Right S	I	12065-G/E/N/Y/P/B/R/K/W/V
Fork Holder Child Right M	I	12066-G/E/N/Y/P/B/R/K/W/V
Fork Holder Child Left S	I	13065-G/E/N/Y/P/B/R/K/W/V
Fork Holder Child Left M	I	13066-G/E/N/Y/P/B/R/K/W/V
Fork Holder Adult Right L	I	12068-G/E/N/Y/P/B/R/K/W/V
Fork Holder Adult Right XL	I	12069-G/E/N/Y/P/B/R/K/W/V
Fork Holder Adult Left L	I	13068-G/E/N/Y/P/B/R/K/W/V

Fork Holder Adult Left XL	I	13069-G/E/N/Y/P/B/R/K/W/V
Sponge Tube Child	I	10071-G/E/N/Y/P/B/R/K/W/V
Sponge Tube Adult	I	10073-G/E/N/Y/P/B/R/K/W/V
Writing Loop S Kit	I	10501-G/E/N/Y/P/B/R/K/W/V
Writing Loop M Kit	I	10503-G/E/N/Y/P/B/R/K/W/V
Writing Loop L Kit	I	10505-G/E/N/Y/P/B/R/K/W/V
Pair of Heat Gloves XL	I	10707-G/E/N/Y/P/B/R/K/W/V
Pair of Heat Gloves Large	I	10705-G/E/N/Y/P/B/R/K/W/V
Pair of Heat Gloves Medium	I	10703-G/E/N/Y/P/B/R/K/W/V
Cassit Towel	I	10801-G/E/N/Y/P/B/R/K/W/V
Cassit water bath Small	I	60001-G/E/N/Y/P/B/R/K/W/V
Cassit water bath Medium + White Bottom	I	60002-G/E/N/Y/P/B/R/K/W/V
Cassit water bath Large	I	60003-G/E/N/Y/P/B/R/K/W/V
Tongs Small	I	60011-G/E/N/Y/P/B/R/K/W/V
Tongs Medium	I	60013-G/E/N/Y/P/B/R/K/W/V
Tongs Large	I	60015-G/E/N/Y/P/B/R/K/W/V

- 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= Gray, G = Green. Black = K, White=W, V=Various
- The text in the brackets might not be included in the product name on the packaging.
- MS = Medium Small

Name: Tamar Ish Cassit

Title: Co-CEO

Date: 02/08/2021

Signature: 