# DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of Össur hf.

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| **Manufacturer's name:** | Össur hf. |
| **Manufacturer SRN:** | IS-MF-000000173 |
| **Business address:** | Grjóthláls 1-5<br>110 Reykjavík<br>Iceland |
| **Basic UDI-DI:** | See attached list of medical devices |
| **Medical device(s):** | See attached list of medical devices |
| **Intended purpose:** | See attached list of medical devices |
| **Risk Class:** | See attached list of medical devices |
| **GMDN/EMDN code:** | See attached list of medical devices |

The devices covered by this declaration are in conformity with Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Class I products follow the procedure set out in Annex VII of the Medical Device Directive 93/42 EEC, as amended.

**UK designated standards:**

EN ISO 22523 External limb prostheses and external orthoses – Requirements and test methods.

EN IEC 62366 Application of usability engineering to medical devices

EN ISO 14971 Application of Risk Management to medical devices

EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice

EN 1041 Information supplied by the manufacturer of medical devices

EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EN IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements

EN 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

EN 62304 Medical device software – Software life cycle processes

EN ISO 17664 Processing of health care products - Information to be provided by the medical device

manufacturer for the processing of medical devices

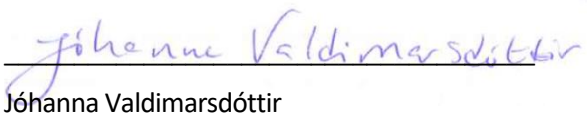
EN ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

EN ISO 10328 Prosthetics – Structural testing of lower-limb prostheses – Requirements and test methods

EN ISO 22675 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods

**Authorised signatory:**

Reykjavík, 2022-11-11



Jóhanna Valdimarsdóttir

Quality and Regulatory Director, Person Responsible for Regulatory Compliance (PRRC)

**List of medical devices**

| Basic UDI-DI | Medical device | Intended purpose | Risk Class | GMDN | EMDN |
|---|---|---|---|---|---|
| 5690967BU00001MT | Iceross Seal-In® X | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 41536 | Y062409 |
| | Iceross Dermo Seal-In® | | I | 41536 | Y062409 |
| | Iceross Seal-In® V | | I | 41536 | Y062409 |
| | Iceross Seal-In® X5 | | I | 41536 | Y062409 |
| | Iceross Seal-In® X TF | | I | 41536 | Y062415 |
| | Iceross Seal-In® X5 TF | | I | 41536 | Y062415 |
| | Iceross Seal-In® Transfemoral | | I | 41536 | Y062415 |
| | 4Seal Classic | | I | 41536 | Y062499 |
| | 4Seal Senso | | I | 41536 | Y062415 |
| | Iceross Seal-In® X Seals | | I | 41536 | Y062499 |
| 5690967BU00002MV | Iceross® Synergy Cushion | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 41536 | Y062409 |
| | Iceross Dermo® Cushion | | I | 41536 | Y062409 |
| | Iceross Dermo® Uniform Cushion | | I | 41536 | Y062409 |
| | Iceross Comfort® Cushion | | I | 41536 | Y062409 |
| | Iceross® Activa Cushion | | I | 41536 | Y062409 |
| | Relax Cushion | | I | 41536 | Y062409 |
| | Protect Cushion | | I | 41536 | Y062409 |
| 5690967BU00003MX | Iceross® Synergy Locking | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 41536 | Y062409 |
| | Iceross Dermo® Locking | | I | 41536 | Y062409 |
| | Iceross Dermo® Uniform Locking | | I | 41536 | Y062409 |
| | Iceross Comfort® Locking | | I | 41536 | Y062409 |
| | Iceross® Original Locking | | I | 41536 | Y062409 |
| | Iceross® Sport Locking | | I | 41536 | Y062409 |
| | Iceross® Transfemoral Locking | | I | 41536 | Y062415 |

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|---|---|---|---|---|---|
| | Iceross Stabilo® Junior Locking | | I | 41536 | Y062409 |
| | Iceross Dermo® Junior Locking | | I | 41536 | Y062409 |
| | AKOS | | I | 41536 | Y062415 |
| | Relax Transfemoral | | I | 41536 | Y062415 |
| | Relax Locking | | I | 41536 | Y062409 |
| | Sensitive Locking | | I | 41536 | Y062409 |
| | Soft C | | I | 41536 | Y062409 |
| | Protect Locking | | I | 41536 | Y062409 |
| | First | | I | 41536 | Y062409 |
| | Aspire™ Locking | | I | 41536 | Y062499 |
| 5690967BU00004MZ | Iceross® Upper-X Locking | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing upper limb. | I | 41536 | Y061899 |
| 5690967BU00005N3 | Iceform® Locking Liner | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 41536 | Y062409 |
| 5690967BU00006N5 | Iceross® Sleeve | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 64715 | Y062409 |
| | Iceflex® Balance Sleeve | | I | 64715 | Y062409 |
| 5690967BU00007N7 | Iceform® Sleeve | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 64715 | Y062409 |
| | Genu Sleeve | | I | 64715 | Y062409 |
| 5690967BU00008N9 | Iceross® Distal Cup | The device is a prosthetic interface intended to be used as part of a system that replaces a missing lower limb. | I | 41536 | Y062499 |
| | Iceross® Pads | | I | 41536 | Y062499 |
| | Pressure pads | | I | 41536 | Y062499 |
| 5690967BU00009NB | Iceross® Interface Sheath | The device is intended to be used for prosthetic socket donning. | I | 41536 | Y062499 |
| 5690967BU00010MU | Iceross® Socks | The device is intended to be used for accommodating residual limb volume reduction. | I | 41536 | Y062499 |
| | Iceross Seal-In® Socks | | I | 41536 | Y062499 |

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| | Volume Compensation Sock | | I | 41536 | Y062499 |
| 5690967BU00011MW | Iceform® Cushion Liner | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 41536 | Y062409 |
| 5690967BU00012MY | Iceross® Direct Casting Liner | The device is intended to both fabricate and become a socket. The socket is intended as a part of a prosthetic system that replaces a missing lower limb. | I | 41536 | Y062409 |
| | Direct Socket Tool Kit | | I | 64714 | Y0699 |
| | Össur Brim | | I | 64714 | Y062415 |
| | Direct Socket TT | | I | 64714 | Y062409 |
| | Direct Socket TF | | I | 64714 | Y062415 |
| 5690967BU00013N2 | Iceross Seal-In® X Locking | The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb. | I | 41536 | Y062409 |
| 5690967BU00014N4 | Iceross® Post-Op TT | The device is intended to compress the residual limb as part of post-operative treatment after amputation. | I | 41536 | Y062409 |
| | Iceross® Post-Op TF | | I | 41536 | Y062415 |
| 5690967BU00015N6 | Össur Rigid Dressing | The device is intended to immobilize, protect and control post-operative edema in the residual limb. | I | 35358 | Y062409 |
| 5690967BU00016N8 | Rebound® Knee | The device is intended for external support or stabilization of the knee. | I | 41065 | Y061209 |
| | Formfit® Hinged Knees | | I | 41065 | Y061209 |
| | Formfit® Knee Hinged Lateral J | | I | 41065 | Y061209 |
| | Neoprene Knee Sleeve | | I | 41065 | Y061209 |
| | Formfit® Knee MCL | | I | 41065 | Y061209 |
| | Neoprene Hinged Knee Support | | I | 41065 | Y061209 |
| | Neoprene Knee Support with Stabilized Patella | | I | 41065 | Y061209 |
| | Neoprene Wraparound Hinged Knee Support | | I | 41065 | Y061209 |
| | Formfit® ROM Knees | | I | 41065 | Y061209 |
| 5690967BU00017NA | Battery dummy | The device is a tool for aiding the fitting, setup or | I | 64717 | Y062499 |

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| | Vacuum Pump for Rigid Dressing | donning of a prosthetic component. | I | 64717 | Y062499 |
| 5690967BU00018NC | CTi® Custom | The device is intended for external support, stabilization and protection of the knee. | I | 41065 | Y061209 |
| | CTi® | | I | 41065 | Y061209 |
| | Flex® | | I | 41065 | Y061209 |
| | C180™ Rocket | | I | 41065 | Y061209 |
| | Paradigm® | | I | 41065 | Y061209 |
| | Paradigm® Custom | | I | 41065 | Y061209 |
| | CTi®3 | | I | 41065 | Y061209 |
| 5690967BU00019NE | FX® Patella stabilizer | The device is intended for external support or stabilization of the patella. | I | 41065 | Y061209 |
| | Formfit® Pro Knee Quest | | I | 41065 | Y061209 |
| | Formfit® Tracker | | I | 41065 | Y061209 |
| 5690967BU00020MX | Formfit® Pro Ankle | The device is intended for increased proprioception and compression of the ankle. | I | 36206 | Y06120601 |
| 5690967BU00021MZ | Elastic Abdominal Binder | The device is intended to provide compression and support to the abdominal area. | I | 33031 | Y060499 |
| 5690967BU00023N5 | Miami JTO® Thoracic Extension | The device is intended to restrict movement in the low cervical and high thoracic spine. | I | 41453 | Y060315 |
| 5690967BU00024N7 | Front Closure Clavicle Support | The device is intended to pull the shoulders back. | I | 13810 | Y060699 |
| | Figure-8 Clavicle Splint | | I | 13810 | Y060699 |
| 5690967BU00025N9 | Formfit® Tennis Elbow | The device is intended to relieve pain due to epicondylitis. | I | 41053 | Y060615 |
| | Airform® Tennis Elbow Support | | I | 41053 | Y060615 |
| | Tennis Elbow Support with Hot/Cold Therapy Gel Pad | | I | 41053 | Y060615 |
| 5690967BU00026NB | Innovator X® Post-Op Elbow | The device is intended to provide controlled range-of-motion for post-traumatic, post-surgical repair of the elbow. | I | 41053 | Y060615 |
| | Rebound® Post-Op Elbow | | I | 41053 | Y060615 |
| 5690967BU00027ND | Formfit® Ankle with Speedlace | The device is intended to support the ankle. | I | 36206 | Y06120601 |
| | Formfit® Ankle with Figure 8 | | I | 36206 | Y06120601 |
| 5690967BU00028NF | Formfit® Pro Elbow | The device is intended for compression and pain | I | 41053 | Y060615 |

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| | | relieve of the elbow. | | | |
| 5690967BU00029NH | Formfit® Foam Ankle Stirrup | The device is intended to support the ankle. | I | 36206 | Y06120601 |
| | Formfit® Honeycomb Ankle Stirrup | | I | 36206 | Y06120601 |
| | AirForm® Universal Inflatable Ankle Stirrup | | I | 36206 | Y06120601 |
| | AirForm® Inflatable Ankle Stirrup | | I | 36206 | Y06120601 |
| | AirForm® Pre-inflated Ankle Stirrup | | I | 36206 | Y06120601 |
| | Gel Ankle Stirrup | | I | 36206 | Y06120601 |
| | Rebound® Ankle Brace | | I | 36206 | Y06120601 |
| | Formfit® Ankle Stirrups | | I | 36206 | Y06120601 |
| | Formfit® Air Ankle Stirrup | | I | 36206 | Y06120601 |
| | Formfit® Gel Ankle Stirrup | | I | 36206 | Y06120601 |
| 5690967BU00030N2 | AFO Dynamic | The device is intended to support drop-foot. | I | 36206 | Y06120602 |
| | AFO Light | | I | 36206 | Y06120602 |
| | Foot-Up® | | I | 36206 | Y06120601 |
| | Rebound Foot-Up® | | I | 36206 | Y06120601 |
| | AFO Leaf Spring | | I | 36206 | Y06120601 |
| 5690967BU00031N4 | Formfit® Night Splint | The device is intended to keep the foot/ankle in a neutral position. | I | 36206 | Y06120601 |
| | Exoform® Dorsal Night Splint | | I | 36206 | Y06120601 |
| | AirForm® Night Splint | | I | 36206 | Y06120601 |
| 5690967BU00032N6 | Rebound® Air Walker | The device is intended for immobilization of the foot and ankle. | I | 36206 | Y06120601 |
| | Rebound® Air Walker LT | | I | 36206 | Y06120601 |
| | Formfit® Walker | | I | 36206 | Y06120601 |
| | Formfit® Walker Air | | I | 36206 | Y06120601 |
| | Pediatric Walker | | I | 36206 | Y06120601 |
| | Metal Strut Air Walker | | I | 36206 | Y06120601 |
| 5690967BU00033N8 | Rebound® Hip | The device is intended for motion restriction of the hip. | I | 36228 | Y061215 |
| 5690967BU00034NA | Unloader® Hip | The device is intended for external rotation, | I | 36228 | Y061215 |

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| | | abduction and/or compression around the hip. | | | |
| 5690967BU00035NC | Rebound® Cartilage | The device is intended for external support or stabilization of the knee. | I | 41065 | Y061209 |
| | Rebound® DUAL Custom | | I | 41065 | Y061209 |
| | Rebound® Cartilage Custom | | I | 41065 | Y061209 |
| | Rebound® DUAL | | I | 41065 | Y061209 |
| | Extreme® | | I | 41065 | Y061209 |
| | Rebound® DUAL ST Custom | | I | 41065 | Y061209 |
| | Rebound® DUAL ST | | I | 41065 | Y061209 |
| | SmartDosing® kit | | I | 41065 | Y061209 |
| | Rebound® DUAL Recover | | I | 41065 | Y061209 |
| | Rebound® DUAL Basic | | I | 41065 | Y061209 |
| | Rebound® DUAL Basic ST | | I | 41065 | Y061209 |
| 5690967BU00036NE | Formfit® Knee Immobilizer | The device is intended to immobilize the knee. | I | 12099 | Y061209 |
| | Exoform® Knee Immobilizer | | I | 12099 | Y061209 |
| | Rebound® Post-Op Knee | | I | 12099 | Y061209 |
| | Formfit® Post-Op Knee | | I | 12099 | Y061209 |
| | Rebound® Knee Immobilizer Universal | | I | 12099 | Y061209 |
| 5690967BU00037NG | Unloader One® | The device is intended for unicompartmental unloading of the knee. | I | 41065 | Y061209 |
| | Unloader One® Custom | | I | 41065 | Y061209 |
| | Unloader One® Plus | | I | 41065 | Y061209 |
| | Unloader® Custom | | I | 41065 | Y061209 |
| | Unloader® Spirit | | I | 41065 | Y061209 |
| | CTi® OA | | I | 41065 | Y061209 |
| | Formfit® OA Wraparound | | I | 41065 | Y061209 |
| | Unloader One® Lite | | I | 41065 | Y061209 |
| | Formfit® Pro Knee OA | | I | 41065 | Y061209 |
| | Unloader One® X | | I | 41065 | Y061209 |

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| | Unloader One® X Custom | | I | 41065 | Y061209 |
| | OA Ease | | I | 41065 | Y061209 |
| 5690967BU00038NJ | Formfit® Back Support | The device is intended to provide gross immobilization of the lumbar spine and/or compression. | I | 33031 | Y060308 |
| | Formfit® Back Support Air | | I | 33031 | Y060308 |
| | Miami LSO™ | | I | 33031 | Y060308 |
| | OAM Rigid Lumbar™ | | I | 33031 | Y060308 |
| | Formfit® Pro Back | | I | 33031 | Y060308 |
| 5690967BU00039NL | Temporary Hernia Support | The device is intended to provide support over the lumbar spine. | I | 33031 | Y060406 |
| 5690967BU00040N5 | Dual Maternity Belt | The device is intended to provide sacroiliac and supra pubic support and reduce lower back pain. | I | 33031 | Y060303 |
| 5690967BU00041N7 | Universal Elastic Rib Belt | The device is intended to support the rib cage. | I | 41042 | Y060307 |
| 5690967BU00042N9 | Formfit® Wrist | The device is intended to restrict motion of the wrist and/or thumb. | I | 41459 | Y060612 |
| | Formfit® Thumb | | I | 41459 | Y060613 |
| | Formfit® Universal Wrist | | I | 41459 | Y060612 |
| | Exoform® Wrist | | I | 41459 | Y060612 |
| | Exoform® Carpal Tunnel Wrist | | I | 41459 | Y060612 |
| | Universal Thumb Splint | | I | 41459 | Y060613 |
| | Elastic Thumb Spica | | I | 41459 | Y060613 |
| | Wrist / Thumb Brace | | I | 41459 | Y060613 |
| | Spectra® Wrist Brace | | I | 41459 | Y060612 |
| | Formfit® Universal Thumb | | I | 41459 | Y060613 |
| | Wrist Brace | | I | 41459 | Y060612 |
| | Thumb Spica | | I | 41459 | Y060613 |
| 5690967BU00043NB | Formfit® Thumb OA Night | The device is intended to stabilize the thumb. | I | 41459 | Y060613 |
| | Formfit® Thumb OA Day | | I | 41459 | Y060613 |
| 5690967BU00044ND | K2 Sensation® with D/P Flexion | The device is intended as a part of a prosthetic system that replaces the foot and ankle function | I | 64724 | Y062403 |
| | Flex-Foot Balance® with D/P Flexion | | I | 64724 | Y062403 |

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| | Pro-Flex® LP Align | of a missing lower limb. | I | 64723 | Y062403 |
| 5690967BU00045NF | Balance™ Foot J | The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb. | I | 64723 | Y062403 |
| | Flex-Foot Assure® | | I | 64723 | Y062403 |
| | Cheetah® Xplore | | I | 64723 | Y062403 |
| | Vari-Flex® Modular | | I | 64723 | Y062403 |
| | Vari-Flex® | | I | 64723 | Y062403 |
| | LP Vari-Flex® | | I | 64723 | Y062403 |
| | Vari-Flex® Junior | | I | 64723 | Y062403 |
| | Flex-Foot® Junior | | I | 64723 | Y062403 |
| | Cheetah® Xplore Junior | | I | 64723 | Y062403 |
| | Aspire™ Foot | | I | 64723 | Y062403 |
| | Balance™ Foot S | | I | 64723 | Y062403 |
| 5690967BU00046NH | Pro-Flex® Pivot | The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb. | I | 64723 | Y062403 |
| | Pro-Flex® XC | | I | 64723 | Y062403 |
| | Pro-Flex® LP | | I | 64723 | Y062403 |
| | Pro-Flex® Modular | | I | 64723 | Y062403 |
| | Pro-Flex® ST | | I | 64723 | Y062403 |
| 5690967BU00047NK | Flex-Symes™ | The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb. | I | 64723 | Y062403 |
| | Chopart | | I | 64723 | Y062403 |
| 5690967BU00049NP | Flex-Foot Balance® | The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb. | I | 64723 | Y062403 |
| | Talux® | | I | 64723 | Y062403 |
| | K2 Sensation® | | I | 64723 | Y062403 |
| 5690967BU00050N8 | Flex-Run™ | The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb. | I | 64723 | Y062403 |
| | Flex-Foot Cheetah® | | I | 64723 | Y062403 |
| | Cheetah® Xtreme | | I | 64723 | Y062403 |
| | Cheetah® Xtend | | I | 64723 | Y062403 |
| | Cheetah® Junior | | I | 64723 | Y062403 |

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| | Flex-Run™ Junior | | I | 64723 | Y062403 |
| | Cheetah® Xceed | | I | 64723 | Y062403 |
| | Cheetah® Xcel | | I | 64723 | Y062403 |
| | Cheetah® Xpanse | | I | 64723 | Y062403 |
| 5690967BU00051NA | Re-Flex Rotate™ | The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb. | I | 64723 | Y062403 |
| | Re-Flex Shock™ | | I | 64723 | Y062403 |
| | Pro-Flex® XC Torsion | | I | 64723 | Y062403 |
| | Pro-Flex® LP Torsion | | I | 64723 | Y062403 |
| | Balance™ Foot S Torsion | | I | 64723 | Y062403 |
| 5690967BU00054NG | Total Knee® 1900 | The device is intended as a part of a prosthetic system that replaces knee function of a missing lower limb. | I | 64718 | Y062415 |
| | Total Knee® 2000 | | I | 64719 | Y062415 |
| | Total Knee® 2100 | | I | 64719 | Y062415 |
| | Cheetah® Knee | | I | 64719 | Y062415 |
| | Total Knee® Junior | | I | 64718 | Y062415 |
| | Balance™ Knee OFM1 | | I | 64718 | Y062415 |
| | Balance™ Knee OM8 | | I | 64718 | Y062415 |
| | OH5 Knee | | I | 64719 | Y062415 |
| | OH7 Knee | | I | 64719 | Y062415 |
| | OHP3 Knee | | I | 64719 | Y062415 |
| | OP5 Knee | | I | 64719 | Y062415 |
| | Paso Knee | | I | 64719 | Y062415 |
| | OP2 Knee | | I | 64719 | Y062415 |
| | Aspire™ M2 | | I | 64718 | Y062415 |
| | Aspire™ H1 | | I | 64719 | Y062415 |
| | Aspire™ P1 | | I | 64719 | Y062415 |
| 5690967BU00055NJ | Mauch® Knee | The device is intended as a part of a prosthetic system that replaces knee function of a missing | I | 64719 | Y062415 |
| | Mauch® Knee Plus | | I | 64719 | Y062415 |

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| | OP4 Knee | lower limb. | I | 64719 | Y062415 |
| | Haiti Knee | | I | 64718 | Y062415 |
| | Aspire™ M3 | | I | 64718 | Y062415 |
| 5690967BU00056NL | i-Limb® Access | The device is intended as a part of a prosthetic system that replaces the function of a missing upper limb. | I | 41497 | Y061803 |
| | i-Limb® Quantum titanium | | I | 41497 | Y061803 |
| | i-Limb® Access titanium | | I | 41497 | Y061803 |
| | i-Digits™ Quantum | | I | 41486 | Y061803 |
| | i-Limb® Quantum | | I | 41497 | Y061803 |
| | i-Limb® Ultra | | I | 41497 | Y061803 |
| | i-Limb® Ultra titanium | | I | 41497 | Y061803 |
| | i-Digits™ | | I | 41486 | Y061803 |
| | i-Digits™ Access | | I | 41486 | Y061803 |
| | i-Limb Wrist | | I | 41091 | Y061809 |
| 5690967BU00058NQ | Unity® | The device is intended as a part of a prosthetic system that provides suspension via subatmospheric pressure. | I | 64716 | Y062499 |
| 5690967BU00059NS | Comfort SCS | The device is intended to provide compression therapy. | I | 42811 | Y062499 |
| 5690967BU00060NB | Locking Knee | The device is intended as a part of a prosthetic system that replaces knee function of a missing lower limb. | I | 64718 | Y062415 |
| | Balance™ Knee OFM2 | | I | 64718 | Y062415 |
| | Aspire™ M1 | | I | 64718 | Y062415 |
| 5690967BU00061ND | Dual Density Shin Fairing | The device is intended to protect the prosthesis and/or to restore the appearance of a missing limb. | I | 64737 | Y062703 |
| | Single Density Shin Fairing Block | | I | 64737 | Y062703 |
| | Continuous Cosmetic Foam | | I | 64737 | Y062703 |
| | Shin Foam | | I | 64737 | Y062703 |
| | Season Guard | | I | 64736 | Y090399 |

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| | Knee cap, jr | | I | 64736 | Y090399 |
| | Knee caps | | I | 64736 | Y090399 |
| | Discontinuous cosmetic foam | | I | 64737 | Y062703 |
| | Calf cosmesis | | I | 64737 | Y062703 |
| | Shin Ferrule For Balance Knee | | I | 64736 | Y090399 |
| | Shin Fairing, Black | | I | 64736 | Y090399 |
| | Junior Shin Ferrule | | I | 64736 | Y090399 |
| 5690967BU00063NH | Miami Lumbar® Posteo | The device is intended to provide gross immobilization of the thoracic and lumbar spine. | I | 43445 | Y060309 |
| | Miami TLSO™ 464 | | I | 43445 | Y060309 |
| | Miami TLSO™ 456 | | I | 43445 | Y060309 |
| 5690967BU00065NM | Bergschultz Universal Arm Sling | The device is intended to hold the arm in an elevated fixed position. | I | 13622 | Y060630 |
| | Pediatric Universal Arm Sling | | I | 13622 | Y060630 |
| | Premium Padded Arm Sling | | I | 13622 | Y060630 |
| | Premium Contact Closure Arm Sling | | I | 13622 | Y060630 |
| | Buckle Closure Arm Sling | | I | 13622 | Y060630 |
| | High Arm Sling | | I | 13622 | Y060630 |
| | Monitor Arm Sling | | I | 13622 | Y060630 |
| 5690967BU00066NP | Sling and Swathe | The device is intended to immobilize the shoulder and/or elbow. | I | 12101 | Y060630 |
| | Formfit® Shoulder Brace | | I | 12101 | Y060630 |
| | Shoulder Abduction Sling | | I | 12101 | Y060630 |
| | Premium Shoulder Immobiliser | | I | 12101 | Y060630 |
| | Padded Strap Shoulder Immobilizer | | I | 12101 | Y060630 |
| | Premium Shoulder Immobilizer | | I | 12101 | Y060630 |
| 5690967BU00067NR | Rebound® PCL Custom | The device is intended for dynamic support and stabilization of ligaments of the knee. | I | 41065 | Y061209 |
| | Rebound® ACL Custom | | I | 41065 | Y061209 |
| | Rebound® PCL | | I | 41065 | Y061209 |
| | Rebound® ACL | | I | 41065 | Y061209 |

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| 5690967BU00068NT | Miami J® | The device is intended to provide gross immobilization to the cervical spine. | I | 41039 | Y060312 |
| | Papoose® | | I | 41032 | Y060312 |
| | Miami Jr® | | I | 41039 | Y060312 |
| | Philadelphia® Adjustable Tracheotomy Collar | | I | 41039 | Y060312 |
| | Philadelphia® Tracheotomy Collar | | I | 41039 | Y060312 |
| | NecLoc® | | I | 41039 | Y060312 |
| | NecLoc® Kids | | I | 41039 | Y060312 |
| | Patriot® Collar | | I | 41039 | Y060312 |
| | Miami J® Select | | I | 41039 | Y060312 |
| | Occian® Back | | I | 41039 | Y060312 |
| 5690967BU00069NV | Philadelphia Stabilizer | The device is intended to enhance gross immobilization of the cervical spine. | I | 41039 | Y060312 |
| 5690967BU00070NE | 4-Hole Socket Adapter AL | The device is intended as a connection component of a prosthetic system that replaces a missing lower limb. | I | 61229 | Y062499 |
| | Male Insert For Prong AL | | I | 61229 | Y062499 |
| | Female Insert For Prong SS | | I | 61229 | Y062499 |
| | 4-Hole Male Pyramid Adapter AL | | I | 61229 | Y062499 |
| | 4-Hole Female Pyramid Adapter AL | | I | 61229 | Y062499 |
| | Threaded 4-Hole Socket Adapter AL | | I | 61229 | Y062499 |
| | Male Tube Clamp AL | | I | 61229 | Y062499 |
| | Female Tube Clamp AL | | I | 61229 | Y062499 |
| | 4-Hole Tube Clamp AL | | I | 61229 | Y062499 |
| | Male Single Adapter AL | | I | 61229 | Y062499 |
| | Female Single Adapter AL | | I | 61229 | Y062499 |
| | Female Double Adapter AL | | I | 61229 | Y062499 |
| | Male Double Adapter AL | | I | 61229 | Y062499 |
| | Tube | | I | 61229 | Y062499 |
| | Female Pylon AL | | I | 61229 | Y062499 |

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| | Female Pylon Kit 100kg | | I | 61229 | Y062499 |
| | SACH Foot Adapter AL | | I | 61229 | Y062499 |
| | 4-Hole Female Pyramid Adapter 20/20 Offset AL | | I | 61229 | Y062499 |
| | Male-Female Double Adapter With Offset | | I | 61229 | Y062499 |
| | Male Socket Adapter | | I | 61229 | Y062499 |
| | 4-Hole Socket Adapter TI | | I | 61229 | Y062499 |
| | 4-Prong Socket Adapter | | I | 61229 | Y062499 |
| | 3-Prong Socket Adapter | | I | 61229 | Y062499 |
| | Male Insert For Prong TI | | I | 61229 | Y062499 |
| | Female Insert For Prong TI | | I | 61229 | Y062499 |
| | Female Insert For Prong LP TI | | I | 61229 | Y062499 |
| | 4-Hole Male Pyramid Adapter TI | | I | 61229 | Y062499 |
| | 4-Hole Male Pyramid Adapter Rotation TI | | I | 61229 | Y062499 |
| | 4-Hole Male Pyramid Adapter 8mm Offset TI | | I | 61229 | Y062499 |
| | 4-Hole Female Pyramid Adapter TI | | I | 61229 | Y062499 |
| | 4-Hole Female Pyramid Adapter Rotation TI | | I | 61229 | Y062499 |
| | Male Tube Clamp TI | | I | 61229 | Y062499 |
| | Female Tube Clamp TI | | I | 61229 | Y062499 |
| | 4-Hole Tube Clamp TI | | I | 61229 | Y062499 |
| | Male Single Adapter TI | | I | 61229 | Y062499 |
| | Female Single Adapter TI | | I | 61229 | Y062499 |
| | Female Double Adapter TI | | I | 61229 | Y062499 |
| | Male Double Adapter TI | | I | 61229 | Y062499 |
| | SACH Foot Adapter TI | | I | 61229 | Y062499 |
| | Female Double Adapter with Shift | | I | 61229 | Y062499 |

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| | Icelock® 672 Male Pyramid TI | | I | 61229 | Y062499 |
| | Icelock® 673 Male Pyramid AL | | I | 61229 | Y062499 |
| | Icelock® 674 4-Hole Adapter AL | | I | 61229 | Y062499 |
| | Icelock® 675 4-Hole Adapter TI | | I | 61229 | Y062499 |
| | Icelock® 773 Male Pyramid AL | | I | 61229 | Y062499 |
| | Icelock® 774 4-Hole Adapter AL | | I | 61229 | Y062499 |
| | 4-Prong Socket Adapter Junior | | I | 61229 | Y062499 |
| | Female Insert For Prong Junior | | I | 61229 | Y062499 |
| | Male Insert For Prong Junior | | I | 61229 | Y062499 |
| | 4-Hole Socket Adapter Junior | | I | 61229 | Y062499 |
| | 4-Hole Male Pyramid Adapter Junior | | I | 61229 | Y062499 |
| | 4-Hole Female Pyramid Adapter Junior | | I | 61229 | Y062499 |
| | Female Tube Clamp Junior | | I | 61229 | Y062499 |
| | Tube Junior | | I | 61229 | Y062499 |
| | SACH Foot Adapter Junior | | I | 61229 | Y062499 |
| | 4-Hole Male Pyramid Adapter Rotation SS | | I | 61229 | Y062499 |
| | 4-Hole Female Pyramid Adapter Rotation SS | | I | 61229 | Y062499 |
| | 4-Hole Connection Plate | | I | 61229 | Y062499 |
| | Icelock® 272 Male Pyramid TI | | I | 61229 | Y062499 |
| | Icelock® 273 Male Pyramid SS | | I | 61229 | Y062499 |
| | Icelock® 600 XM Male Pyramid | | I | 61229 | Y062499 |
| | Icelock® 600 XM Socket Adapter | | I | 61229 | Y062499 |
| | Icelock® 600 Series Spacer For Direct Socket | | I | 61229 | Y062499 |
| | Height Adjustable Pylon | | I | 61229 | Y062499 |
| | Threaded Female Pyramid Adapter | | I | 61229 | Y062499 |
| | Threaded Male Pyramid Adapter TI | | I | 61229 | Y062499 |

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| | Threaded Male Pyramid Adapter SS | | I | 61229 | Y062499 |
| | Female Pylon TI WP | | I | 61229 | Y062499 |
| | Height Adjustable Pylon Junior | | I | 61229 | Y062499 |
| | Threaded Male Pyramid Adapter Junior | | I | 61229 | Y062499 |
| | Female Pylon AL TI | | I | 61229 | Y062499 |
| | Female Pylon Kit 166 kg | | I | 61229 | Y062499 |
| 5690967BU00072NJ | Formfit® Pro Wrist | The device is intended to provide support and compression of the wrist. | I | 41459 | Y060612 |
| 5690967BU00073NL | DH Offloading Post-Op Style Shoe | The device is intended for foot protection post injury and plantar off loading. | I | 41435 | Y063303 |
| | Square Toe Post-Op Shoe | | I | 41435 | Y063303 |
| 5690967BU00074NN | Rebound® Diabetic Walker | The device is intended for plantar surface offloading and immobilization. | I | 36206 | Y06120601 |
| | DH Offloading Walker | | I | 36206 | Y06120601 |
| 5690967BU00075NQ | Soft Top Post-Op Shoe | The device is intended to accommodate the foot and dressings post injury. | I | 41435 | Y063303 |
| | Mesh Top Post-Op Shoe Male | | I | 41435 | Y063303 |
| | Mesh Top Post-Op Shoe Female | | I | 41435 | Y063303 |
| 5690967BU00076NS | Icelock® 125 Ratchet | The device is intended to connect and release a prosthetic system that replaces a missing lower limb. | I | 64715 | Y062499 |
| | Icelock® 211 Clutch | | I | 64715 | Y062499 |
| | Icelock® 214 4-Hole Clutch | | I | 64715 | Y062499 |
| | Icelock® 214 Clutch AK Offset | | I | 64715 | Y062499 |
| | Icelock® 400 Standard Lamination | | I | 64715 | Y062499 |
| | Icelock® 400 Single / Double Lamination | | I | 64715 | Y062499 |
| | Icelock® 400 BOA-System Lamination | | I | 64715 | Y062499 |
| | Icelock® 400 Single Lamination with 4-hole Adapter | | I | 64715 | Y062499 |
| | Icelock® 621 Ratchet | | I | 64715 | Y062499 |
| | Icelock® 651 Smooth | | I | 64715 | Y062499 |

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| | Icelock® 721 Ratchet | | I | 64715 | Y062499 |
| | Icelock® 125 Ratchet Fabrication Kit Without Braid | | I | 64715 | Y062499 |
| | Icelock® 125 Ratchet Fabrication Kit With Braid | | I | 64715 | Y062499 |
| | Icelock® 600XM Ratchet | | I | 64715 | Y062499 |
| | Icelock® 621 Ratchet Adaption Kit | | I | 64715 | Y062499 |
| | Icelock® 214 Clutch DS | | I | 64715 | Y062499 |
| | Icelock® 651 Smooth Adaption Kit | | I | 64715 | Y062499 |
| 5690967BU00077NU | Canvas Rocker Bottom Cast Shoe | The device is intended for weight bearing while using cast. | I | 32462 | Y061203 |
| 5690967BU00078NW | Icelock® 551 Expulsion Valve | The device is intended to connect and release a prosthetic system that replaces a missing lower limb. | I | 64715 | Y062499 |
| | Icelock® 552 Expulsion Valve TF | | I | 64715 | Y062499 |
| | Icelock® 641 Valve | | I | 64715 | Y062499 |
| | Icelock® 544 Unity Kit | | I | 64715 | Y062499 |
| | Icelock® 544 Expulsion Kit | | I | 64715 | Y062499 |
| | Icelock® 544 EP Kit | | I | 64715 | Y062499 |
| | Icelock® 544 Reservoir Kit | | I | 64715 | Y062499 |
| | Icelock® 544 LL Kit | | I | 64715 | Y062499 |
| | Icelock® 544 Expulsion Valve Kit | | I | 64715 | Y062499 |
| | Icelock® 544 E2 Connector Kit | | I | 64715 | Y062499 |
| | Icelock® 544 Unity Plate | | I | 64715 | Y062499 |
| | Icelock® 544 Expulsion Plate | | I | 64715 | Y062499 |
| | Icelock® 544 EP Plate | | I | 64715 | Y062499 |
| | Icelock® 544 Reservoir Plate | | I | 64715 | Y062499 |
| | Icelock® 544 LL Plate | | I | 64715 | Y062499 |
| | Icelock® 544 Expulsion Valve | | I | 64715 | Y062499 |
| | Icelock® 544 E2 Connector | | I | 64715 | Y062499 |

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| | Vacu Valve | | I | 64715 | Y062499 |
| | Unity® Valve TT | | I | 64715 | Y062499 |
| | Unity® Valve TF | | I | 64715 | Y062499 |
| | Icelock® 641 Valve Adaption Kit | | I | 64715 | Y062499 |
| 5690967BU00079NY | Foam Cervical Collar | The device is intended to provide cervical support. | I | 41039 | Y060312 |
| | Universal Cervical Collar | | I | 41039 | Y060312 |
| 5690967BU00081NK | Anterior panels | The device is intended to enhance gross lumbar spine immobilization. | I | 43445 | Y060380 |
| | Posterior panels | | I | 43445 | Y060380 |
| | Non-lordotic posterior panels | | I | 43445 | Y060380 |
| | Anterior panel standard & pendulous | | I | 43445 | Y060380 |
| | Posterior panels without Lateral support | | I | 43445 | Y060380 |
| | Posterior panels with Lateral support | | I | 43445 | Y060380 |
| | Posterior panels with Cutout and Lateral support | | I | 43445 | Y060380 |
| | Posterior panel Standard | | I | 43445 | Y060380 |
| 5690967BU00082NM | Adhesive Insole for Wedge | The device is intended to plantar flex the foot. | I | 36206 | Y061280 |
| | Achilles Heel Wedge | | I | 36206 | Y061280 |
| 5690967BU00083NP | FSE Foot cover | The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb. | I | 64736 | Y090399 |
| | FCLA Foot cover | | I | 64736 | Y090399 |
| | FCPE Foot cover | | I | 64736 | Y090399 |
| | FST Foot cover | | I | 64736 | Y090399 |
| | FSF Foot cover | | I | 64736 | Y090399 |
| | FCT Foot cover | | I | 64736 | Y090399 |
| | FSM Foot cover | | I | 64736 | Y090399 |
| | FJS Foot cover | | I | 64736 | Y090399 |
| | FSL Foot Cover | | I | 64736 | Y090399 |
| 5690967BU00084NR | Ski boot attachment | The device is intended to secure the brace to a ski boot. | I | 41065 | Y061280 |

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| 5690967BU00085NT | Elastic Calf Suspension Strap | The device is intended to keep brace in place, increase comfort and/or protect skin. | I | 41065 | Y061280 |
| | Softsleeve | | I | 41065 | Y061280 |
| | AMS Sleeve | | I | 41065 | Y061280 |
| | Lycra Liner | | I | 41065 | Y061280 |
| | Undersleeve | | I | 41065 | Y061280 |
| | Condyle Pad Kit | | I | 41065 | Y061280 |
| | Anti-Migration System (AMS) Wrap EVA | | I | 41065 | Y061280 |
| | AMS Wrap NEO - CTi® Custom | | I | 41065 | Y061280 |
| | Undersleeve Neoprene | | I | 41065 | Y061280 |
| | Oversleeve Neoprene | | I | 41065 | Y061280 |
| | Padded Sports Oversleeve | | I | 41065 | Y061280 |
| | Thigh/Calf liner EVA | | I | 41065 | Y061280 |
| | Neo AMS Wrap for CTi® OTS | | I | 41065 | Y061280 |
| | Silicone AMS Wrap | | I | 41065 | Y061280 |
| | Suspension Strap Kit | | I | 41065 | Y061280 |
| | AMS Wrap | | I | 41065 | Y061280 |
| | Non-elastic Thigh Strap | | I | 41065 | Y061280 |
| | Strap and Pad Kit | | I | 41065 | Y061280 |
| | Philadelphia Liner | | I | 41039 | Y060380 |
| 5690967BU00086NV | OR kit | The device is intended to protect ankle and perineum skin intraoperatively and/or providing motion restriction of the hip. | I | 36228 | Y061280 |
| 5690967BU00087NX | Foam wedge | The device is intended to increase dorsiflexion. | I | 36206 | Y061280 |
| 5690967BU00088NZ | Stability Strap Kit | The device is intended to enhance support/stability around the ankle. | I | 36206 | Y061280 |
| 5690967BU00089P3 | Protector Sleeve | The device is intended to protect a prosthetic suspension liner or sleeve from wear and tear. | I | 64715 | Y062499 |

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| 5690967BU00090NL | Icelock® 331 Lamination Sockets | The device is intended to connect and release a prosthetic system that replaces a missing lower limb. | I | 64715 | Y062499 |
| | Icelock® 331 Thermoplastic Sockets | | I | 64715 | Y062499 |
| | Icelock® 234 Lanyard | | I | 64715 | Y062499 |
| | Icelock® 631 Lanyard | | I | 64715 | Y062499 |
| | Icelock® 234 Lanyard Adaptation Kit | | I | 64715 | Y062499 |
| | Icelock® 631 Lanyard Adaption Kit | | I | 64715 | Y062499 |
| 5690967BU00091NN | Axilla pillow | The device is intended to enhance immobilization of the shoulder joint. | I | 12101 | Y060680 |
| | External rotation pillow | | I | 12101 | Y060680 |
| 5690967BU00092NQ | Belt Extender | The device is intended to increase the circumference of a medical device. | I | 36228 | Y061280 |
| | Strap Extension | | I | 36206 | Y061280 |
| | Width Extender kit | | I | 36206 | Y061280 |
| 5690967BU00094NU | Hot/Cold Therapy Gel Pad | The device is intended for hot/cold therapy. | I | 37240 | Y0699 |
| 5690967BU00095NW | Torsion Shock Adapter | The device is intended as a part of a prosthetic system that replaces function of a missing limb by managing vertical and rotational forces. | I | 64731 | Y062403 |
| 5690967BU00096NY | Relax Night Care | The device is intended to aid in the reduction of phantom pain. | I | 13635 | Y090618 |
| 5690967BU00097P2 | Connect® TF | The device is a pre-assembled, size adjustable socket intended as a part of a prosthetic system that replaces a missing lower limb. | I | 64713 | Y062415 |
| 5690967BU00098P4 | Icelock® 562 Hybrid Unity | The device is intended to connect and release a prosthetic system that replaces a missing lower limb. | I | 64715 | Y062499 |
| | Icelock® 562 Hybrid Unity Connector | | I | 64715 | Y062499 |
| | Icelock® 562 Hybrid Passive Vacuum DS | | I | 64715 | Y062499 |
| | Icelock® 562 Hybrid Passive Vacuum | | I | 64715 | Y062499 |
| | Icelock® 562 Hybrid Unity DS | | I | 64715 | Y062499 |
| | Icelock® 562 Hybrid Outlet Port | | I | 64715 | Y062499 |
| 5690967BU00100MW | Nike Sole | The device is intended as a part of a prosthetic system that replaces the foot and ankle function | I | 64736 | Y062403 |
| | Nike Spike Pad | | I | 64736 | Y062403 |

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| | Nike SoleX | of a missing lower limb. | I | 64736 | Y062403 |
| | Nike SoleX Attachment Kit | | I | 64736 | Y062403 |
| 5690967BU00101MY | Knee Rotation Adapter | The device is intended as a part of a system that replaces function of a missing limb. It connects the knee joint with the proximal part of the prosthesis and allows for inward and outward rotation of the knee joint. | I | 61229 | Y062499 |
| 5690967BU00102N2 | MX Kit | The device is intended to decrease impact forces. | I | 41065 | Y061280 |
| | MX Patella Cup | | I | 41065 | Y061280 |
| | MX Gear Guards | | I | 41065 | Y061280 |
| | Patella cup | | I | 41065 | Y061280 |
| | Knee shield | | I | 41065 | Y061280 |
| | CTi®3 Impact Guard | | I | 41065 | Y061280 |
| 5690967BU00103N4 | Formfit® Pro Knee | The device is intended for compression around the knee and external support or stabilization of the patella. | I | 41065 | Y061209 |
| | Formfit® Pro Knee Flite | | I | 41065 | Y061209 |
| 5690967BU00105N8 | SoftWalk Insoles | The device is intended to provide shock absorption. | I | 41575 | Y061203 |
| 5690967BU00107NC | Extension Stop Kit | The device is intended to enhance support/stability around the knee. | I | 41065 | Y061280 |
| | PCL Kit for CTi® | | I | 41065 | Y061280 |
| | Flexion Stop Kit | | I | 41065 | Y061280 |
| | CTi®3 PCL Strap | | I | 41065 | Y061280 |
| 5690967BU00108NE | Knee lanyard kit for Connect® TF | The device is intended to manually lock or unlock a mechanical prosthetic knee. | I | 64713 | Y062415 |
| 5690967BU00111N3 | Livingskin® fingers | The device is intended to impart some of the aesthetic and supporting functions of a missing limb. | I | 41078 | Y061803 |
| | Livingskin® | | I | 41078 | Y061803 |
| 5690967BU00112N6 | Formfit Knee Buttress | The device is intended to enhance patella | I | 41065 | Y061280 |

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| | | stabilization. | | | |