

## DECLARATION OF CONFORMITY

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

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

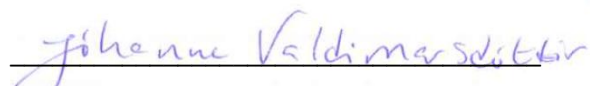
EN ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

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, 2025-04-03



Jóhanna Valdimarsdóttir

VP of Quality and Regulatory, 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

	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	Y062409
	Aspire™ TF Locking		I	41536	Y062415
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	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	I	41536	Y062499

	Iceross Seal-In® Socks	accommodating residual limb volume reduction.	I	41536	Y062499
	Volume Compensation Sock		I	41536	Y062499
5690967BU00011MW	Iceform® 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
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
	AeroFit® Socket		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
	Iceross Seal-In® X Locking TF		I	41536	Y062415
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	Vacuum Pump for Rigid Dressing	The device is a tool for aiding the fitting, setup or 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	66086	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.		36206	Y06120601
	Formfit® Ankle			36206	Y06120601
5690967BU00028NF	Formfit® Pro Elbow	The device is intended for compression and pain relieve of the elbow.		41053	Y060615
5690967BU00029NH	Formfit® Foam Ankle Stirrup	The device is intended to support the ankle.		36206	Y06120601
	Formfit® Honeycomb Ankle Stirrup			36206	Y06120601
	AirForm® Universal Inflatable Ankle Stirrup			36206	Y06120601
	AirForm® Inflatable Ankle Stirrup			36206	Y06120601
	AirForm® Pre-inflated Ankle Stirrup			36206	Y06120601
	Gel Ankle Stirrup			36206	Y06120601
	Rebound® Ankle Brace			36206	Y06120601
	Formfit® Ankle Stirrup			36206	Y06120601
	Formfit® Air Ankle Stirrup			36206	Y06120601
	Formfit® Gel Ankle Stirrup			36206	Y06120601
5690967BU00030N2	AFO Dynamic	The device is intended to support drop-foot.		36206	Y06120602
	AFO Light			36206	Y06120602
	Foot-Up®			36206	Y06120601
	Rebound Foot-Up®			36206	Y06120601
	AFO Leaf Spring			36206	Y06120601
5690967BU00031N4	Formfit® Night Splint	The device is intended to keep the foot/ankle in a neutral position.		36206	Y06120601
	Exoform® Dorsal Night Splint			36206	Y06120601
	AirForm® Night Splint			36206	Y06120601
5690967BU00032N6	Rebound® Air Walker	The device is intended for immobilization of the foot and ankle.		36206	Y06120601
	Rebound® Air Walker LT			36206	Y06120601
	Formfit® Walker			36206	Y06120601
	Formfit® Walker Air			36206	Y06120601

	Pediatric Walker		I	36206	Y06120601
	Metal Strut Air Walker		I	36206	Y06120601
5690967BU00033N8	Rebound <sup>®</sup> Hip	The device is intended for motion restriction of the hip.	I	36228	Y061215
5690967BU00034NA	Unloader <sup>®</sup> Hip	The device is intended for external rotation, abduction and/or compression around the hip.	I	36228	Y061215
5690967BU00035NC	Rebound <sup>®</sup> DUAL Custom	The device is intended for external support or stabilization of the knee.	I	41065	Y061209
	Rebound <sup>®</sup> DUAL		I	41065	Y061209
	Extreme <sup>®</sup>		I	41065	Y061209
	Rebound <sup>®</sup> DUAL ST Custom		I	41065	Y061209
	Rebound <sup>®</sup> DUAL ST		I	41065	Y061209
	SmartDosing <sup>®</sup> kit		I	41065	Y061209
	Rebound <sup>®</sup> DUAL Recover		I	41065	Y061209
	Rebound <sup>®</sup> DUAL Basic		I	41065	Y061209
	Rebound <sup>®</sup> DUAL Basic ST		I	41065	Y061209
5690967BU00036NE	Formfit <sup>®</sup> Knee Immobilizer	The device is intended to immobilize the knee.	I	12099	Y061209
	Exoform <sup>®</sup> Knee Immobilizer		I	12099	Y061209
	Rebound <sup>®</sup> Post-Op Knee		I	12099	Y061209
	Formfit <sup>®</sup> Post-Op Knee		I	12099	Y061209
	Rebound <sup>®</sup> Knee Immobilizer Universal		I	12099	Y061209
5690967BU00037NG	Unloader One <sup>®</sup>	The device is intended for unicompartmental unloading of the knee.	I	41065	Y061209
	Unloader One <sup>®</sup> Custom		I	41065	Y061209
	Unloader One <sup>®</sup> Plus		I	41065	Y061209
	Unloader <sup>®</sup> Custom		I	41065	Y061209
	Unloader <sup>®</sup> Spirit		I	41065	Y061209
	CTi <sup>®</sup> OA		I	41065	Y061209
	Formfit <sup>®</sup> OA Wraparound		I	41065	Y061209
	Unloader One <sup>®</sup> Lite		I	41065	Y061209



	Formfit® Pro Knee OA		I	41065	Y061209
	Unloader One® X		I	41065	Y061209
	Unloader One® X Custom		I	41065	Y061209
	OA Ease		I	41065	Y061209
	Rebound® Cartilage		I	41065	Y061209
	Rebound® Cartilage Custom		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
	Formfit® Back VS		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 of a missing lower limb.	I	64724	Y062403
	Flex-Foot® Balance with D/P Flexion		I	64724	Y062403
	Pro-Flex® LP Align		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® Terra		I	64723	Y062403
	Pro-Flex® ST		I	64723	Y062403
	Pro-Flex® LP Junior		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

5690967BU00048NM	Proprio Foot®	The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower limb.	I	64725	Y062409
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
	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
5690967BU00053NE	Rheo Knee® XC	The device is intended as a part of a prosthetic system that replaces knee function of a missing lower limb.	I	64721	Y062415
	Rheo Knee®		I	64721	Y062415
	Navii®		I	64721	Y062415
5690967BU00054NG	Total Knee® 1900	The device is intended as a part of a prosthetic system that replaces knee function of a missing	I	64718	Y062415
	Total Knee® 2000		I	64719	Y062415

	Total Knee® 2100	lower limb.	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 lower limb.	I	64719	Y062415
	Mauch® Knee Plus		I	64719	Y062415
	OP4 Knee		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
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
	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	66086	Y060309
	Miami TLSO™ 464		I	66086	Y060309
	Miami TLSO™ 456		I	66086	Y060309
5690967BU00065NM	Bergschultz Universal Arm Sling	The device is intended to hold the arm in an elevated fixed position.	I	12101	Y060630
	Pediatric Universal Arm Sling		I	12101	Y060630
	Premium Padded Arm Sling		I	12101	Y060630
	Premium Contact Closure Arm Sling		I	12101	Y060630

	Buckle Closure Arm Sling		I	12101	Y060630
	High Arm Sling		I	12101	Y060630
	Monitor Arm Sling		I	12101	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
5690967BU00068NT	Miami J®	The device is intended to provide gross immobilization to the cervical spine.	I	41039	Y060312
	Papoose®		I	66086	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	I	61229	Y062499
	Male Insert For Prong		I	61229	Y062499

Female Insert For Prong SS
4-Hole Male Pyramid Adapter AL
4-Hole Female Pyramid Adapter AL
Threaded 4-Hole Socket Adapter AL
Male Tube Clamp AL
Female Tube Clamp AL
4-Hole Tube Clamp AL
Male Single Adapter AL
Female Single Adapter AL
Female Double Adapter AL
Male Double Adapter AL
Tube
Female Pylon AL
Female Pylon Kit 100kg
SACH Foot Adapter AL
4-Hole Female Pyramid Adapter 20/20 Offset AL
Male-Female Double Adapter With Offset SS
Male Socket Adapter TI
4-Hole Socket Adapter TI
4-Prong Socket Adapter SS
3-Prong Socket Adapter SS
Male Insert For Prong TI
Female Insert For Prong TI
Female Insert For Prong LP TI
4-Hole Male Pyramid Adapter TI
4-Hole Male Pyramid Adapter Rotation TI

lower limb.

I	61229	Y062499
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4-Hole Male Pyramid Adapter 8mm Offset TI
4-Hole Female Pyramid Adapter TI
4-Hole Female Pyramid Adapter Rotation TI
Male Tube Clamp TI
Female Tube Clamp TI
4-Hole Tube Clamp TI
Male Single Adapter TI
Female Single Adapter TI
Female Double Adapter TI
Male Double Adapter TI
SACH Foot Adapter TI
Female Double Adapter with Shift TI
Icelock® 672 Male Pyramid TI
Icelock® 673 Male Pyramid AL
Icelock® 674 4-Hole Adapter AL
Icelock® 675 4-Hole Adapter TI
Icelock® 773 Male Pyramid AL
Icelock® 774 4-Hole Adapter AL
4-Prong Socket Adapter Junior
Female Insert For Prong Junior
Male Insert For Prong Junior
4-Hole Socket Adapter Junior
4-Hole Male Pyramid Adapter Junior
4-Hole Female Pyramid Adapter Junior
Female Tube Clamp Junior
Tube Junior

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	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
	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
	Female Single Adapter Junior		I	61229	Y062499
	Flexion Plate		I	61229	Y062499
	Female Single Adapter 5mm Offset Junior		I	61229	Y062499
	Female Insert For Prong LP Ti Junior		I	61229	Y062499
	Icelock® 772 Male Pyramid Ti		I	61229	Y062499
	Adult Male to Junior Female Double Adapter		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
	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	I	32462	Y061203

		using cast.			
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
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	66086	Y060380
	Posterior panels		I	66086	Y060380
	Non-lordotic posterior panels		I	66086	Y060380

	Anterior panel standard & pendulous		I	66086	Y060380
	Posterior panels without Lateral support		I	66086	Y060380
	Posterior panels with Lateral support		I	66086	Y060380
	Posterior panels with Cutout and Lateral support		I	66086	Y060380
	Posterior panel Standard		I	66086	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
	FSW Foot Cover	I	64736	Y090399	
5690967BU00084NR	Ski boot attachment	The device is intended to secure the brace to a ski boot.	I	41065	Y061280
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
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
	Icelock® 850 Hybrid for Direct Socket		I	64715	Y062499
	Icelock® 850 Hybrid for Laminated Socket		I	64715	Y062499
	Icelock® 850 Hybrid for 4-Hole Socket		I	64715	Y062499
5690967BU00100MW	Nike Sole	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	Y062403
	Nike Spike Pad		I	64736	Y062403
	Nike SoleX		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	I	61229	Y062499

		knee joint.			
5690967BU00102N2	MX Kit	The device is intended to decrease impact forces.		41065	Y061280
	MX Patella Cup			41065	Y061280
	MX Gear Guards			41065	Y061280
	Patella cup			41065	Y061280
	Knee shield			41065	Y061280
	CTi <sup>®</sup> 3 Impact Guard			41065	Y061280
5690967BU00103N4	Formfit <sup>®</sup> Pro Knee	The device is intended for compression around the knee and external support or stabilization of the patella.		41065	Y061209
	Formfit <sup>®</sup> Pro Knee Flite			41065	Y061209
5690967BU00105N8	SoftWalk Insoles	The device is intended to provide shock absorption.		41575	Y061203
5690967BU00107NC	Extension Stop Kit	The device is intended to enhance support/stability around the knee.		41065	Y061280
	PCL Kit for CTi <sup>®</sup>			41065	Y061280
	Flexion Stop Kit			41065	Y061280
	CTi <sup>®</sup> 3 PCL Strap			41065	Y061280
5690967BU00108NE	Knee lanyard kit for Connect <sup>®</sup> TF	The device is intended to manually lock or unlock a mechanical prosthetic knee.		64713	Y062415
5690967BU00109NG	AeroFit <sup>®</sup> Seal-In	The device is a prosthetic interface with suspension properties intended to be used as part of a system that replaces a missing lower limb.		41536	Y062499
5690967BU00111N3	Livingskin <sup>®</sup> fingers	The device is intended to impart some of the aesthetic and supporting functions of a missing limb.		41078	Y061803
	Livingskin <sup>®</sup>			41078	Y061803
5690967BU00112N6	Formfit Knee Buttress	The device is intended to enhance patella stabilization.		41065	Y061280