

DECLARATION OF CONFORMITY

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

Manufacturer's name: Össur hf.
Manufacturer SRN: IS-MF-000000173
Business address: Grjótháls 1-5
110 Reykjavík
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 regulation (EU) 2017/745 of the European parliament and of the council.

Class I products follow the procedure set out in Article 19, Annex II and Annex III.

Class II products follow the procedure set out in Annex IX.

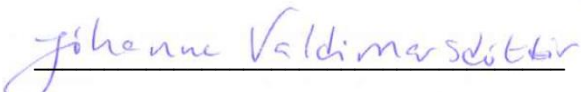
Notified Body: BSI Group The Netherlands B.V.
Identification number: 2797

CE Certificate

Össur hf. is certified to Full Quality Assurance by BSI (certificate no. MDR 738259), i.e. to fully comply with the requirements of Regulation (EU) 2017/745, Annex IX Chapter I and III.

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
	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
	Volume Compensation Sock		I	41536	Y062499
5690967BU00011MW	Iceform® Cushion Liner	The device is a prosthetic interface with	I	41536	Y062409

		suspension properties intended to be used as part of a system that replaces a missing lower limb.			
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 donning of a prosthetic component.	I	64717	Y062499
	Vacuum Pump for Rigid Dressing		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 relieve of the elbow.	I	41053	Y060615
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, abduction and/or compression around the hip.	I	36228	Y061215
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
	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 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® 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
	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
5690967BU00052NC	Power Knee™	The device is intended as a part of a prosthetic system that replaces knee function of a missing lower limb.	Ila	64722	Y062415
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 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	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
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
	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		

	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
	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
	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
	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
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
5690967BU00099P6	Össur Logic	The device is intended to provide a digital interface to prosthetic devices supporting wireless communication.	IIa	64734	Z129082
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 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

5690967BU00106NA	Power Knee Battery	The device is an accessory intended to provide electrical energy to a medical device, enabling its intended purpose.	IIa	36534	Y062415
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 stabilization.	I	41065	Y061280