

## DECLARATION OF CONFORMITY

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

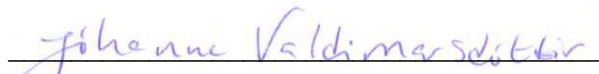
**Manufacturer's name:** Össur hf.  
**Manufacturer SRN:** IS-MF-000000173  
**Business address:** Grjótháls 1-5  
110 Reykjavík  
Iceland  
**Basic UDI-DI:** See attached list of medical devices  
**Medical device(s):** See attached list of medical devices  
**Intended purpose:** See attached list of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

**Authorised signatory:**

Reykjavík, 2021-12-14



Jóhanna Valdimarsdóttir

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

**List of medical devices**

<b>Basic UDI-DI</b>	<b>Medical device</b>	<b>Intended purpose</b>	<b>GMDN</b>	<b>CND</b>
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.	41536	Y062499
	Iceross Dermo Seal-In®		41536	Y062499
	Iceross Seal-In® V		41536	Y062499
	Iceross Seal-In® X5		41536	Y062499
	Iceross Seal-In® X TF		41536	Y062499
	Iceross Seal-In® X5 TF		41536	Y062499
	Iceross Seal-In® Transfemoral		41536	Y062499
	4Seal Classic		41536	Y062499
	4Seal Senso		41536	Y062499
	Iceross Seal-In® X Seals		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.	41536	Y062499
	Iceross Dermo® Cushion		41536	Y062499
	Iceross Dermo® Uniform Cushion		41536	Y062499
	Iceross Comfort® Cushion		41536	Y062499
	Iceross® Activa Cushion		41536	Y062499
	Relax Cushion		41536	Y062499
	Protect Cushion		41536	Y062499
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.	41536	Y062499
	Iceross Dermo® Locking		41536	Y062499
	Iceross Dermo® Uniform Locking		41536	Y062499
	Iceross Comfort® Locking		41536	Y062499
	Iceross® Original Locking		41536	Y062499
	Iceross® Sport Locking		41536	Y062499
	Iceross® Transfemoral Locking		41536	Y062499
	Iceross Stabilo® Junior Locking		41536	Y062499
	Iceross Dermo® Junior Locking		41536	Y062499

	AKOS		41536	Y062499
	Relax Transfemoral		41536	Y062499
	Relax Locking		41536	Y062499
	Sensitive Locking		41536	Y062499
	Soft C		41536	Y062499
	Protect Locking		41536	Y062499
	First		41536	Y062499
	Aspire Locking		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.	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.	41536	Y062499
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.	64715	Y062499
	Icelflex® Balance Sleeve		64715	Y062499
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.	64715	Y062499
	Genu Sleeve		64715	Y062499
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.	41536	Y062499
	Iceross® Pads		41536	Y062499
	Pressure pads		41536	Y062499
5690967BU00009NB	Iceross® Interface Sheath	The device is intended to be used for prosthetic socket donning.	41536	Y062499
5690967BU00010MU	Iceross® Socks	The device is intended to be used for accommodating residual limb volume reduction.	41536	Y062499
	Iceross Seal-In® Socks		41536	Y062499
	Volume Compensation Sock		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.	41536	Y062499

5690967BU00012MY	Iceross® Direct Casting Liner	The devices are 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.	41536	Y062499
	Direct Socket Tool Kit		64714	Y0699
	Össur Brim		64714	Y062415
	Direct Socket TT		64714	Y62409
	Direct Socket TF		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.	41536	Y062499
5690967BU00014N4	Iceross® Post-Op TT	The device is intended to compress the residual limb as part of post-operative treatment after amputation.	41536	Y062499
	Iceross® Post-Op TF		41536	Y062499
5690967BU00015N6	Rigid Dressing	The device is intended to immobilize, protect and control post-operative edema in the residual limb.	35358	Y062499
5690967BU00016N8	Rebound® Knee	The device is intended for external support or stabilization of the knee.	41065	Y061209
	Formfit® Hinged Knees		41065	Y061209
	Formfit® Knee Hinged Lateral J		41065	Y061209
	Neoprene Knee Sleeve		41065	Y061209
	Formfit® Knee MCL		41065	Y061209
	Neoprene Hinged Knee Support		41065	Y061209
	Neoprene Knee Support with Stabilized Patella		41065	Y061209
	Neoprene Wraparound Hinged Knee Support		41065	Y061209
	Formfit® ROM Knees		41065	Y061209
5690967BU00017NA	Icelock® 680 Fabrication Tooling	The device is a tool for aiding the fitting, setup or donning of a prosthetic component.	64717	Y062499
	Icelock® 780 Fabrication Tooling		64717	Y062499
	Icelock® 400 Fixture for all lock kits		64717	Y062499
	Icelock® 400 Dummy for P20191 & P20191-X		64717	Y062499
	Icelock® 400 Dummy for P20192		64717	Y062499
	Icelock® 400 Dummy for P20194		64717	Y062499

	Battery dummy		64717	Y062499
	Vacuum Pump for Rigid Dressing		64717	Y062499
	Smart Cast Tool		64717	Y062499
5690967BU00018NC	CTi® Custom	The device is intended for external support, stabilization and protection of the knee.	41065	Y061209
	CTi®		41065	Y061209
	Flex®		41065	Y061209
	C180™ Rocket		41065	Y061209
	Paradigm®		41065	Y061209
	Paradigm® Custom		41065	Y061209
5690967BU00019NE	FX® Patella stabilizer	The device is intended for external support or stabilization of the patella.	41065	Y061209
	Formfit® Pro Knee Quest		41065	Y061209
	Formfit® Tracker		41065	Y061209
5690967BU00020MX	Formfit® Pro Ankle	The device is intended for increased proprioception and compression of the ankle.	36206	Y061209
5690967BU00021MZ	Elastic Abdominal Binder	The device is intended to provide compression and support to the abdominal area.	33031	Y060308
5690967BU00023N5	Miami JTO® Thoracic Extension	The device is intended to restrict movement in the low cervical and high thoracic spine.	41453	Y060315
5690967BU00024N7	Front Closure Clavicle Support	The device is intended to pull the shoulders back.	13810	Y060699
	Figure-8 Clavicle Splint		13810	Y060699
5690967BU00025N9	Formfit® Tennis Elbow	The device is intended to relieve pain due to epicondylitis.	41053	Y060615
	Airform® Tennis Elbow Support		41053	Y060615
	Tennis Elbow Support with Hot/Cold Therapy Gel Pad		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.	41053	Y060615
	Rebound® Post-Op Elbow		41053	Y060615
5690967BU00027ND	Formfit® Ankle with Speedlace	The device is intended to support the ankle.	36206	Y061206
	Formfit® Ankle with Figure 8		36206	Y061206
5690967BU00028NF	Formfit® Pro Elbow	The device is intended for compression and pain relieve	41053	Y060615

		of the elbow.		
5690967BU00029NH	Formfit® Foam Ankle Stirrup	The device is intended to support the ankle.	36206	Y061206
	Formfit® Honeycomb Ankle Stirrup		36206	Y061206
	AirForm® Universal Inflatable Ankle Stirrup		36206	Y061206
	AirForm® Inflatable Ankle Stirrup		36206	Y061206
	AirForm® Pre-inflated Ankle Stirrup		36206	Y061206
	Gel Ankle Stirrup		36206	Y061206
	Rebound® Ankle Brace		36206	Y061206
	Formfit® Ankle Stirrups		36206	Y061206
	Formfit® Air Ankle Stirrup		36206	Y061206
	Formfit® Gel Ankle Stirrup		36206	Y061206
5690967BU00030N2	AFO Dynamic	The device is intended to support drop-foot.	36206	Y061206
	AFO Light		36206	Y061206
	Foot-Up®		36206	Y061206
	Rebound Foot-Up®		36206	Y061206
	AFO Leaf Spring		36206	Y061206
5690967BU00031N4	Formfit® Night Splint	The device is intended to keep the foot/ankle in a neutral position.	36206	Y061206
	Exoform® Dorsal Night Splint		36206	Y061206
	AirForm® Night Splint		36206	Y061206
5690967BU00032N6	Rebound® Air Walker	The device is intended for immobilization of the foot and ankle.	36206	Y061206
	Rebound® Air Walker LT		36206	Y061206
	Formfit® Walker		36206	Y061206
	Formfit® Walker Air		36206	Y061206
	Pediatric Walker		36206	Y061206
	Metal Strut Air Walker		36206	Y061206
5690967BU00033N8	Rebound® Hip	The device is intended for motion restriction of the hip.	36228	Y061215
5690967BU00034NA	Unloader® Hip	The device is intended for external rotation, abduction and/or compression around the hip.	36228	Y061215

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

5690967BU00038NJ	Formfit® Back Support	The device is intended to provide gross immobilization of the lumbar spine and/or compression.	33031	Y060308
	Formfit® Back Support Air		33031	Y060308
	Miami LSO™		33031	Y060308
	OAM Rigid Lumbar™		33031	Y060308
	Formfit® Pro Back		33031	Y060308
5690967BU00039NL	Temporary Hernia Support	The device is intended to provide support over the lumbar spine.	33031	Y060308
5690967BU00040N5	Dual Maternity Belt	The device is intended to provide sacroiliac and supra pubic support and reduce lower back pain.	33031	Y060308
5690967BU00041N7	Universal Elastic Rib Belt	The device is intended to support the rib cage.	41042	Y060309
5690967BU00042N9	Formfit® Wrist	The device is intended to restrict motion of the wrist and/or thumb.	41459	Y060612
	Formfit® Thumb		41459	Y060612
	Formfit® Universal Wrist		41459	Y060612
	Exoform® Wrist		41459	Y060612
	Exoform® Carpal Tunnel Wrist		41459	Y060612
	Universal Thumb Splint		41459	Y060612
	Elastic Thumb Spica		41459	Y060612
	Wrist / Thumb Brace		41459	Y060612
	Spectra® Wrist Brace		41459	Y060612
	Formfit® Universal Thumb		41459	Y060612
5690967BU00043NB	Formfit® Thumb OA Night	The device is intended to stabilize the thumb.	41459	Y060612
	Formfit® Thumb OA Day		41459	Y060612
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.	64724	Y062403
	Flex-Foot Balance® with D/P Flexion		64724	Y062403
	Pro-Flex® LP Align		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.	64723	Y062403
	Flex-Foot Assure®		64723	Y062403
	Cheetah® Xplore		64723	Y062403
	Vari-Flex® Modular		64723	Y062403



	Vari-Flex®		64723	Y062403
	LP Vari-Flex®		64723	Y062403
	Vari-Flex® Junior		64723	Y062403
	Flex-Foot® Junior		64723	Y062403
	Cheetah® Xplore Junior		64723	Y062403
	Aspire™ Foot		64723	Y062403
	Balance™ Foot S		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.	64723	Y062403
	Pro-Flex® XC		64723	Y062403
	Pro-Flex® LP		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.	64723	Y062403
	Chopart		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.	64723	Y062403
	Talux®		64723	Y062403
	K2 Sensation®		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.	64723	Y062403
	Flex-Foot Cheetah®		64723	Y062403
	Cheetah® Xtreme		64723	Y062403
	Cheetah® Xtend		64723	Y062403
	Cheetah® Junior		64723	Y062403
	Flex-Run™ Junior		64723	Y062403
	Cheetah® Xceed		64723	Y062403
	Cheetah® Xcel		64723	Y062403
	Cheetah® Xpanse		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.	64723	Y062403
	Re-Flex Shock™		64723	Y062403
	Pro-Flex® XC Torsion		64723	Y062403
	Pro-Flex® LP Torsion		64723	Y062403

	Balance™ Foot S Torsion		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.	64718	Y062415
	Total Knee® 2000		64719	Y062415
	Total Knee® 2100		64719	Y062415
	Cheetah® Knee		64719	Y062415
	Total Knee® Junior		64718	Y062415
	Balance™ Knee OFM1		64718	Y062415
	Balance™ Knee OM8		64718	Y062415
	OH5 Knee		64719	Y062415
	OH7 Knee		64719	Y062415
	OHP3 Knee		64719	Y062415
	OP5 Knee		64719	Y062415
	Paso Knee		64719	Y062415
	OP2 Knee		64719	Y062415
	Aspire™ M2		64718	Y062415
	Aspire™ H1		64719	Y062415
Aspire™ P1	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.	64719	Y062415
	Mauch® Knee Plus		64719	Y062415
	OP4 Knee		64719	Y062415
	Haiti Knee		64718	Y062415
5690967BU00056NL	i-Limb® Access	The device is intended as a part of a prosthetic system that replaces function of a missing upper limb.	41497	Y061803
	i-Limb® Quantum titanium		41497	Y061803
	i-Limb® Access titanium		41497	Y061803
	i-Digits™ Quantum		41486	Y061803
	i-Limb® Quantum		41497	Y061803
	i-Limb® Ultra		41497	Y061803
	i-Limb® Ultra titanium		41497	Y061803

	i-Digits™		41486	Y061803
	i-Digits™ Access		41486	Y061803
	i-Limb Wrist		41091	Y061809
5690967BU00058NQ	Unity®	The device is intended as a part of a prosthetic system that provides suspension via subatmospheric pressure.	64716	Y062499
5690967BU00059NS	Comfort SCS	The device is intended to provide compression therapy.	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.	64718	Y062415
	Balance™ Knee OFM2		64718	Y062415
	Aspire™ M1		64718	Y062415
	Aspire™ M3		64718	Y062415
5690967BU00061ND	Dual Density Shin Fairing	The device is intended to protect the prosthesis and to restore the appearance of a missing limb.	64737	Y062703
	Single Density Shin Fairing Block		64737	Y062703
	Continuous Cosmetic Foam		64737	Y062703
	Shin Foam		64737	Y062703
	Season Guard		64736	Y062499
	Knee cap, jr		64736	Y062499
	Knee caps		64736	Y062499
	Discontinuous cosmetic foam		64737	Y062703
	Calf cosmesis		64737	Y062703
	Shin Ferrule For Balance Knee		64736	Y062499
	Bionic Protector		64736	Y062499
	Shin Fairing, Black		64736	Y062499
	Junior Shin Ferrule		64736	Y062499
	Livingskin®		41078	Y061803
5690967BU00063NH	Miami Lumbar® Posteo	The device is intended to provide gross immobilization of the thoracic and lumbar spine.	43445	Y060309
	Miami TLSO™ 464		43445	Y060309
	Miami TLSO™ 456		43445	Y060309
5690967BU00065NM	Bergschultz Universal Arm Sling	The device is intended to hold the arm in an elevated fixed position.	13622	Y060630
	Pediatric Universal Arm Sling		13622	Y060630

	Premium Padded Arm Sling		13622	Y060630
	Premium Contact Closure Arm Sling		13622	Y060630
	Buckle Closure Arm Sling		13622	Y060630
	High Arm Sling		13622	Y060630
	Monitor Arm Sling		13622	Y060630
5690967BU00066NP	Sling and Swathe	The device is intended to immobilize the shoulder and/or elbow.	12101	Y060621
	Formfit® Shoulder Brace		12101	Y060621
	Shoulder Abduction Sling		12101	Y060621
	Premium Shoulder Immobiliser		12101	Y060621
	Padded Strap Shoulder Immobilizer		12101	Y060621
	Premium Shoulder Immobilizer		12101	Y060621
5690967BU00067NR	Rebound® PCL Custom	The device is intended for dynamic support and stabilization of ligaments of the knee.	41065	Y061209
	Rebound® ACL Custom		41065	Y061209
	Rebound® PCL		41065	Y061209
	Rebound® ACL		41065	Y061209
5690967BU00068NT	Miami J®	The device is intended to provide gross immobilization to the cervical spine.	41039	Y060312
	Papoose®		41032	Y060318
	Miami Jr®		41039	Y060312
	Philadelphia® Adjustable Tracheotomy Collar		41039	Y060312
	Philadelphia® Tracheotomy Collar		41039	Y060312
	NecLoc®		41039	Y060312
	NecLoc® Kids		41039	Y060312
	Patriot® Collar		41039	Y060312
	Miami J® Select		41039	Y060312
	Occian® Back		41039	Y060312
5690967BU00069NV	Philadelphia Tracheotomy Attachment – Stabilizer	The device is intended to enhance gross immobilization of the cervical spine.	41039	Y060312
	Philadelphia Tracheotomy Attachment –		41039	Y060312

	Halo			
5690967BU00070NE	4-Hole Socket Adapter AL	The device is intended as a connection component of a prosthetic system that replaces a missing lower limb.	61229	Y062499
	Male Insert For Prong AL		61229	Y062499
	Female Insert For Prong SS		61229	Y062499
	4-Hole Male Pyramid Adapter AL		61229	Y062499
	4-Hole Female Pyramid Adapter AL		61229	Y062499
	Threaded 4-Hole Socket Adapter AL		61229	Y062499
	Male Tube Clamp AL		61229	Y062499
	Female Tube Clamp AL		61229	Y062499
	4-Hole Tube Clamp AL		61229	Y062499
	Male Single Adapter AL		61229	Y062499
	Female Single Adapter AL		61229	Y062499
	Female Double Adapter AL		61229	Y062499
	Male Double Adapter AL		61229	Y062499
	Tube		61229	Y062499
	Female Pylon AL		61229	Y062499
	Female Pylon Kit 100kg		61229	Y062499
	SACH Foot Adapter AL		61229	Y062499
	4-Hole Female Pyramid Adapter 20/20 Offset AL		61229	Y062499
	Male-Female Double Adapter With Offset		61229	Y062499
	Male Socket Adapter		61229	Y062499
	4-Hole Socket Adapter TI		61229	Y062499
	4-Prong Socket Adapter		61229	Y062499
	3-Prong Socket Adapter		61229	Y062499
Male Insert For Prong TI	61229	Y062499		
Female Insert For Prong TI	61229	Y062499		
Female Insert For Prong LP TI	61229	Y062499		
4-Hole Male Pyramid Adapter TI	61229	Y062499		



	SACH Foot Adapter Junior		61229	Y062499
	4-Hole Male Pyramid Adapter Rotation SS		61229	Y062499
	4-Hole Female Pyramid Adapter Rotation SS		61229	Y062499
	4-Hole Connection Plate		61229	Y062499
	Icelock® 272 Male Pyramid TI		61229	Y062499
	Icelock® 273 Male Pyramid SS		61229	Y062499
	Icelock® 600 XM Male Pyramid		61229	Y062499
	Icelock® 600 XM Socket Adapter		61229	Y062499
	Icelock® 600 Series Spacer For Direct Socket		61229	Y062499
	Height Adjustable Pylon		61229	Y062499
	Threaded Female Pyramid Adapter		61229	Y062499
	Threaded Male Pyramid Adapter TI		61229	Y062499
	Threaded Male Pyramid Adapter SS		61229	Y062499
	Female Pylon TI WP		61229	Y062499
	Height Adjustable Pylon Junior		61229	Y062499
	Threaded Male Pyramid Adapter Junior		61229	Y062499
	Female Pylon AL TI		61229	Y062499
	Female Pylon Kit 166 kg		61229	Y062499
5690967BU00072NJ	Formfit® Pro Wrist	The device is intended to provide support and compression of the wrist.	41459	Y060612
5690967BU00073NL	DH Offloading Post-Op Style Shoe	The device is intended for foot protection post injury and plantar off loading.	41435	Y061206
	Square Toe Post-Op Shoe		41435	Y061206
5690967BU00074NN	Rebound® Diabetic Walker	The device is intended for plantar surface offloading and immobilization.	36206	Y061206
	DH Offloading Walker		36206	Y061206
5690967BU00075NQ	Soft Top Post-Op Shoe	The device is intended to accommodate the foot and dressings post injury.	41435	Y061206
	Mesh Top Post-Op Shoe		41435	Y061206
5690967BU00076NS	Icelock® 125 Ratchet	The device is intended to connect and release a	64715	Y062499

		prosthetic system that replaces a missing lower limb.		
	Icelock® 211 Clutch		64715	Y062499
	Icelock® 214 4-Hole Clutch		64715	Y062499
	Icelock® 214 Clutch AK Offset		64715	Y062499
	Icelock® 400 Standard Lamination		64715	Y062499
	Icelock® 400 Single / Double Lamination		64715	Y062499
	Icelock® 400 BOA-System Lamination		64715	Y062499
	Icelock® 400 Single Lamination with 4-hole Adapter		64715	Y062499
	Icelock® 621 Ratchet		64715	Y062499
	Icelock® 651 Smooth		64715	Y062499
	Icelock® 721 Ratchet		64715	Y062499
	Icelock® 125 Ratchet Fabrication Kit Without Braid		64715	Y062499
	Icelock® 125 Ratchet Fabrication Kit With Braid		64715	Y062499
	Icelock® 600XM Ratchet		64715	Y062499
	Attachment Pin Smooth		64715	Y062499
	Icelock® 621 Ratchet Adaption Kit		64715	Y062499
	Icelock® 214 Clutch DS		64715	Y062499
	Clutch Mechanism and T-Wrench		64715	Y062499
	Attachment Pin Clutch		64715	Y062499
	Attachment Pin Ratchet		64715	Y062499
	Attachment Pin Ratchet Junior		64715	Y062499
	Icelock® 721 Ratchet Pin Adapter		64715	Y062499
	Icelock® 651 Smooth Adaption Kit		64715	Y062499
5690967BU00077NU	Canvas Rocker Bottom Cast Shoe	The device is intended for weight bearing while using cast.	32462	Y061203
5690967BU00078NW	Icelock® 551 Expulsion Valve	The device is intended to connect and release a prosthetic system that replaces a missing lower limb.	64715	Y062499
	Icelock® 552 Expulsion Valve TF		64715	Y062499



	Icelock® 641 Valve		64715	Y062499
	Icelock® 544 Unity Kit		64715	Y062499
	Icelock® 544 Expulsion Kit		64715	Y062499
	Icelock® 544 EP Kit		64715	Y062499
	Icelock® 544 Reservoir Kit		64715	Y062499
	Icelock® 544 LL Kit		64715	Y062499
	Icelock® 544 Expulsion Valve Kit		64715	Y062499
	Icelock® 544 E2 Connector Kit		64715	Y062499
	Icelock® 544 Unity Plate		64715	Y062499
	Icelock® 544 Expulsion Plate		64715	Y062499
	Icelock® 544 EP Plate		64715	Y062499
	Icelock® 544 Reservoir Plate		64715	Y062499
	Icelock® 544 LL Plate		64715	Y062499
	Icelock® 544 Expulsion Valve		64715	Y062499
	Icelock® 544 E2 Connector		64715	Y062499
	Vacu Valve		64715	Y062499
	Unity® Valve TT		64715	Y062499
	Unity® Valve TF		64715	Y062499
	Icelock® 641 Valve Adaption Kit		64715	Y062499
5690967BU00079NY	Foam Cervical Collar	The device is intended to provide cervical support.	41039	Y060312
	Universal Cervical Collar		41039	Y060312
5690967BU00081NK	Anterior panels	The device is intended to enhance gross lumbar spine immobilization.	43445	Y060309
	Posterior panels		43445	Y060309
	Non-lordotic posterior panels		43445	Y060309
	Anterior panel standard & pendulous		43445	Y060309
	Posterior panels without Lateral support		43445	Y060309
	Posterior panels with Lateral support		43445	Y060309
	Posterior panels with Cutout and Lateral support		43445	Y060309

	Posterior panel Standard		43445	Y060309
5690967BU00082NM	Adhesive Insole for wedge	The device is intended to plantar flex the foot.	36206	Y061206
	Achilles heel wedge		36206	Y061206
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.	64736	Y062403
	FCLA Foot cover		64736	Y062403
	FCPE Foot cover		64736	Y062403
	FST Foot cover		64736	Y062403
	FSF Foot cover		64736	Y062403
	FCT Foot cover		64736	Y062403
	FSM Foot cover		64736	Y062403
	FJS Foot cover		64736	Y062403
	FSL Foot Cover		64736	Y062403
5690967BU00084NR	Ski boot attachment	The device is intended to secure the brace to a ski boot.	41065	Y061209
5690967BU00085NT	Elastic Calf Suspension Strap	The device is intended to keep brace in place, increase comfort and/or protect skin.	41065	Y061209
	Softsleeve		41065	Y061209
	AMS Sleeve		41065	Y061209
	Lycra Liner		41065	Y061209
	Undersleeve		41065	Y061209
	Condyle Pad Kit		41065	Y061209
	Anti-Migration System (AMS) Wrap EVA		41065	Y061209
	AMS Wrap NEO - CTi® Custom		41065	Y061209
	Undersleeve Neoprene		41065	Y061209
	Oversleeve Neoprene		41065	Y061209
	Padded Sports Oversleeve		41065	Y061209
	Thigh/Calf liner EVA		41065	Y061209
	Neo AMS Wrap for CTi® OTS		41065	Y061209
	Silicone AMS Wrap		41065	Y061209
Suspension Strap Kit	41065	Y061209		

	AMS Wrap		41065	Y061209
	Non-elastic Thigh Strap		41065	Y061209
	Strap and Pad Kit		41065	Y061209
5690967BU00086NV	OR kit	The device is intended to protect ankle and perineum skin intraoperatively and/or providing motion restriction of the hip.	36228	Y061215
5690967BU00087NX	Foam wedge	The device is intended to increase dorsiflexion.	36206	Y061206
5690967BU00088NZ	Stability Strap Kit	The device is intended to enhance support/stability around the ankle.	36206	Y061206
5690967BU00089P3	Protector Sleeve	The device is intended to protect a prosthetic suspension liner or sleeve from wear and tear.	64715	Y062499
5690967BU00090NL	Icelock® 331 Lamination Sockets	The device is intended to connect and release a prosthetic system that replaces a missing lower limb.	64715	Y062499
	Icelock® 331 Thermoplastic Sockets		64715	Y062499
	Icelock® 234 Lanyard		64715	Y062499
	Icelock® 631 Lanyard		64715	Y062499
	Icelock® 234 Lanyard Adaptation Kit		64715	Y062499
	Icelock® 631 Lanyard Adaption Kit		64715	Y062499
5690967BU00091NN	Axilla pillow	The device is intended to enhance immobilization of the shoulder joint.	13622	Y060630
	External rotation pillow		13622	Y060630
5690967BU00092NQ	Belt Extender	The device is intended to increase the circumference of a medical device.		Y0699
	Strap Extension			Y0699
	Width Extender kit			Y0699
5690967BU00094NU	Hot/Cold Therapy Gel Pad	The device is intended for hot/cold therapy.	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.	64731	Y062403
5690967BU00096NY	Relax Night Care	The device is intended to aid in the reduction of phantom pain.	13635	Y0699
5690967BU00097P2	Connect® TF	The device is a pre-assembled, size adjustable socket intended as a part of a prosthetic system that replaces a	64713	Y062415

		missing lower limb.		
5690967BU00098P4	Icelock® 562 Hybrid Unity	The device is intended to connect and release a prosthetic system that replaces a missing lower limb.	64715	Y062499
	Icelock® 562 Hybrid Unity Connector		64715	Y062499
	Icelock® 562 Hybrid Passive Vacuum DS		64715	Y062499
	Icelock® 562 Hybrid Passive Vacuum		64715	Y062499
	Icelock® 562 Hybrid Unity DS		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.	64736	Y062403
	Nike Spike Pad		64736	Y062403
	Nike SoleX		64736	Y062403
	Nike SoleX Attachment Kit		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.	61229	Y062499
5690967BU00102N2	MX Kit	The device is intended to decrease impact forces.	41065	Y061209
	MX Patella Cup		41065	Y061209
	MX Gear Guards		41065	Y061209
	Patella cup		41065	Y061209
	Knee shield		41065	Y061209
5690967BU00103N4	Formfit® Pro Knee	The device is intended for compression around the knee and external support or stabilization of the patella.	41065	Y061209
	Formfit® Pro Knee Flite		41065	Y061209
5690967BU00105N8	SoftWalk Insoles	The device is intended to provide shock absorption.	41575	Y061203