

EC DECLARATION OF CONFORMITY CERTIFICATE

We, the company Össur hf, Grjothals 1- 5, 110 Reykjavik, Iceland, hereby declare on our own responsibility that the following Class I, Class IIa and Class IIb product ranges meet all applicable Essential requirements of the Medical Device Directive 93/42 EEC in Annex I.

Class I products follow the procedure set out in Annex VII.

Class IIa and Class IIb products follow the procedure set out in Annex II.

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. CE78541), in respect of:

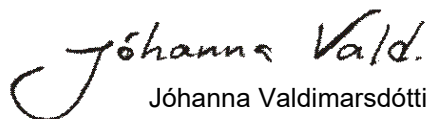
The design and manufacture of microprocessor controlled, powered and non-powered, knee and ankle systems; and sterile and non-sterile cranial traction systems.

Össur runs a quality system according to ISO 13485.

Should you require more detailed information regarding this EC declaration of conformity, please contact Össur Head Office.

This declaration is valid from June 10th 2005.

It was last updated April 30th 2021.



Jóhanna Valdimarsdóttir

Quality & Regulatory Director

ÖSSUR

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Ankle	AFO Dynamic	I	36206	2005.05.01
B&S	Ankle	AFO Light	I	36206	2005.05.01
B&S	Ankle	Airform® Ankle Stirrup	I	36206	bef.2005
B&S	Ankle	Airform® Universal Inflatable Ankle Stirrup	I	36206	2005.07.01
B&S	Ankle	Formfit® Foam Ankle Stirrup	I	36206	bef.2005
B&S	Ankle	Foot-Up™	I	36206	bef.2005
B&S	Ankle	Formfit® Ankle	I	36206	2005.05.01
B&S	Ankle	Formfit® Ankle with Figure 8	I	36206	bef.2005
B&S	Ankle	Formfit® Ankle with Speedlace	I	36206	2005.07.01
B&S	Ankle	Formfit® Ankle Stirrup	I	36206	2020.12.22
B&S	Ankle	Formfit® Air Ankle Stirrup	I	36206	2020.12.22
B&S	Ankle	Formfit® Gel Ankle Stirrup	I	36206	2020.12.22
B&S	Ankle	Formfit® Foam Ankle Stirrup	I	36206	bef.2005
B&S	Ankle	Formfit® Night Splint	I	36206	bef.2005
B&S	Ankle	Formfit® Pro Ankle	I	36206	2018.06.01
B&S	Ankle	Formfit® Walker	I	36206	bef.2005
B&S	Ankle	Formfit® Walker Air	I	36206	2005.07.01
B&S	Ankle	Rebound® Ankle Brace	I	36206	2010.01.01
B&S	Ankle	Rebound® Air Walker	I	36206	2012.06.20

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Ankle	Rebound® Air Walker Low Top	I	36206	2010.10.28
B&S	Ankle	Rebound Foot-Up®	I	36206	17.01.25
B&S	Arm	Bergschultz Universal Arm Sling	I	13622	bef.2005
B&S	Arm	Buckle Closure Arm Sling	I	13622	2018.07.13
B&S	Arm	High Arm Sling	I	13622	2018.07.13
B&S	Arm	Premium Contact Closure Arm Sling	I	13622	2018.07.13
B&S	Arm	Tennis Elbow Support with Hot/Cold Gel Therapy	I	12101	2018.07.13
B&S	Arm & Shoulder	Formfit® Shoulder Brace	I	13622	2016.02.05
B&S	Arm & Shoulder	Monitor Arm Sling	I	13622	bef.2006
B&S	Arm & Shoulder	Premium Padded Arm Sling	I	13622	2018.07.13
B&S	Arm & Shoulder	Padded Strap Shoulder Immobilizer	I	12101	2018.07.13
B&S	Arm & Shoulder	Premium Shoulder Immobilizer	I	12101	bef.2005
B&S	Arm & Shoulder	Shoulder Abduction Sling	I	12101	2018.07.13
B&S	Arm & Shoulder	Sling and Swathe	I	12101	2018.07.13
B&S	Arm & Shoulder	Smartsling®	I	13622	bef.2005
B&S	Back	Airform® Inflatable Back Support	I	33031	bef.2005
B&S	Back	Formfit® Pro Back	I	33031	2018.06.01

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Casting & Splinting	Techform® Ortho-Roll	I	43565	2006.01.01
B&S	Casting & Splinting	Techform® Pre-Cut Splints	I	43565	2006.01.01
B&S	Casting & Splinting	Techform® Premium Cast Tape	I	43565	2010.07.01
B&S	Clavicle	Figure-8 Clavicle Splint	I	13810	bef.2005
B&S	Clavicle	Front Closure Clavicle Support	I	13810	bef.2006
B&S	Elbow	Airform® Tennis elbow	I	41053	bef.2005
B&S	Elbow	Formfit® Pro Elbow	I	41053	2018.06.01
B&S	Elbow	Formfit® Tennis Elbow	I	41053	12.01.02
B&S	Elbow	Carp-X™	I	41459	bef.2005
B&S	Elbow	Innovator X® Post-Op Elbow	I	41053	2006.11.01
B&S	Elbow	Rebound® Post-Op Elbow	I	41053	2020.04.08
B&S	Hand	Elastic Thumb Spica	I	41459	bef.2005
B&S	Hand	Formfit® Thumb OA Day	I	41459	2018.02.02
B&S	Hand	Formfit® Thumb OA Night	I	41459	2018.02.02
B&S	Hand	Formfit® Thumb Spica	I	41459	bef.2005
B&S	Hand	Formfit® Thumb Spica Universal	I	41459	2016.09.15
B&S	Hand	Unloader® Thumb Day	I	41459	2014.12.03
B&S	Hand	Unloader® Thumb Night	I	41459	2014.12.03

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Hand	Universal Thumb Spica	I	41459	2007.04.01
B&S	Hand	Universal Thumb Splint	I	41459	2018.07.13
B&S	Hip	Hip-y	I	36228	2006.01.01
B&S	Hip	Rebound® Hip	I	36228	2013.01.11
B&S	Hip	Unloader® Hip	I	36228	2013.06.27
B&S	Foot	Airform Night Splint®	I	36206	bef.2005
B&S	Foot	AFO Leaf Spring	I	36206	bef.2005
B&S	Foot	DH Offloading Walker™	I	36206	bef.2005
B&S	Foot	Exoform® Dorsal Night Splint	I	36206	2008.08.01
B&S	Foot	Pediatric Walker	I	36206	2018.07.13
B&S	Foot	Rebound Diabetic Walker	I	36206	2014.04.02
B&S	Foot	ROM Walker	I	36206	bef.2005
B&S	Knee	CTi® Custom	I	41065	2007.04.01
B&S	Knee	CTi® OTS	I	41065	2007.04.01
B&S	Knee	CTi® OA	I	41065	2007.04.01
B&S	Knee	C180 Rocket	I	41065	2018.06.21
B&S	Knee	Extreme	I	41065	bef.2005
B&S	Knee	Exoform® Knee Immobilizer	I	12099	bef.2005
B&S	Knee	Flex™	I	41065	2007.04.01

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Knee	Formfit® Hinged Knees	I	41065	2016.02.05
B&S	Knee	Formfit® Knee	I	41065	2018.06.01
B&S	Knee	Formfit® Knee Hinged Lateral J	I	41065	2016.02.05
B&S	Knee	Formfit® Knee Immobilizer Universal	I	12099	2017.02.07
B&S	Knee	Formfit® Knee MCL	I	41065	2016.12.20
B&S	Knee	Formfit® ROM Knees	I	41065	2016.09.15
B&S	Knee	Formfit® OA Wraparound	I	41065	2015.05.26
B&S	Knee	Formfit® OA Ease	I	41065	2020.02.04
B&S	Knee	Formfit® Pro Knee	I	41065	2018.06.06
B&S	Knee	Formfit® Pro Knee Flite	I	41065	2019.10.03
B&S	Knee	Formfit® Pro Knee OA	I	41065	2017.11.17
B&S	Knee	Formfit® Pro Knee Quest	I	41065	2019.10.03
B&S	Knee	Formfit® Post-Op Knee	I	12099	2017.06.08
B&S	Knee	Formfit® Tracker	I	41065	2019.12.20
B&S	Knee	FX™ Patella Stabilizer	I	41065	2018.07.13
B&S	Knee	Genugib Patella	I	41065	2020.05.28
B&S	Knee	Innovator®	I	12099	Bef. 2006
B&S	Knee	Innovator DLX®	I	12099	2006.10.09
B&S	Knee	Innovator DLX® +	I	12099	2012.10.25

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Knee	Neoprene Hinged Knee Support	I	41065	bef. 2005
B&S	Knee	Neoprene Knee Sleeve	I	41065	bef. 2005
B&S	Knee	Neoprene Knee Support with Stabilized Patella	I	41065	bef. 2005
B&S	Knee	Neoprene Wraparound Hinged Knee Support	I	41065	bef. 2005
B&S	Knee	Paradigm® OTS	I	41065	2005.06.10
B&S	Knee	Patella Cup	I	41065	2013.12.31
B&S	Knee	PFOA	I	41065	2014.10.22
B&S	Knee	Rebound® DUAL	I	41065	2015.08.05
B&S	Knee	Rebound® DUAL Basic	I	41065	2021.03.03
B&S	Knee	Rebound® DUAL Basic ST	I	41065	2021.03.03
B&S	Knee	Rebound® DUAL ST	I	41065	2019.03.07
B&S	Knee	Rebound® DUAL Recover	I	41065	2020.09.04
B&S	Knee	Rebound® Knee Brace	I	41065	2011.07.28
B&S	Knee	Rebound® Knee Immobilizer Universal	I	12099	2021.03.03
B&S	Knee	Rebound® ACL	I	41065	2014.09.09
B&S	Knee	Rebound® PCL	I	41065	2014.10.22
B&S	Knee	Rebound® Cartilage	I	41065	2013.06.28
B&S	Knee	Rebound® Cartilage Custom	I	41065	2015.03.05

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Knee	Rebound® Post-Op Knee	I	12099	2017.03.23
B&S	Knee	Trainer®	I	41065	2005.06.10
B&S	Knee	Universal 3-Panel Knee Immobilizer	I	12099	bef. 2005
B&S	Knee	Unloader® ADJ	I	41065	bef. 2005
B&S	Knee	Unloader® Custom	I	41065	bef. 2005
B&S	Knee	Unloader® Express	I	41065	bef. 2005
B&S	Knee	Unloader® Lite	I	41065	bef.2005
B&S	Knee	Unloader® One Lite	I	41065	2017.02.15
B&S	Knee	Unloader® One	I	41065	2010.10.19
B&S	Knee	Unloader® One Custom	I	41065	2010.10.19
B&S	Knee	Unloader® One Plus	I	41065	2011.06.20
B&S	Knee	Unloader® One SmartDosing	I	41065	2012.09.05
B&S	Knee	Unloader One® X	I	41065	2019.05.31
B&S	Knee	Unloader® PF	I	41065	2016.05.10
B&S	Knee	Unloader® Select	I	41065	bef.2005
B&S	Knee	Unloader Spirit®	I	41065	bef.2005
B&S	Knee	Unloader® XT	I	41065	bef.2005
B&S	Knee	Undersleeve	I	41065	2013.04.08
B&S	Other	Canvas Rocker Bottom Cast Shoe	I	32462	bef.2006

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Other	Insoles	I	41575	bef.2005
B&S	Other	DH Offloading Post-Op Shoe	I	41435	2010.01.01
B&S	Other	Mesh Top Post-Op Shoe	I	35381	2018.07.13
B&S	Other	Soft Top Post-Op Shoe	I	35381	2018.07.13
B&S	Other	Thomas Splint	I		2003.10.20
B&S	Spinal	Dual Maternity Belt	I	33031	bef.2006
B&S	Spinal	Foam Cervical Collar	I	41039	2009.01.01
B&S	Spinal	Formfit® Back Support	I	33031	2017.02.07
B&S	Spinal	Formfit® Back Support Air	I	33031	2017.02.07
B&S	Spinal	Miami JTO Thoracic Extension	I	41453	bef.2005
B&S	Spinal	Miami J®	I	41039	bef.2005
B&S	Spinal	Miami J® Advanced	I	41039	2010.07.14
B&S	Spinal	Miami J Select®	I	41039	2018.07.09
B&S	Spinal	Miami Jr®	I	41039	bef.2005
B&S	Spinal	Miami LSO™	I	33031	2017.02.22
B&S	Spinal	Miami Lumbar™ TLSO	I	43445	2010.03.25
B&S	Spinal	Miami Lumber™ Posteo	I	43445	2012.11.09
B&S	Spinal	Miami TLSO 456	I	43445	2019.02.15

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B&S	Spinal	Miami TLSO 464	I	43445	2019.02.15
B&S	Spinal	NecLoc®	I	41039	bef.2005
B&S	Spinal	NecLoc® Kids	I	41039	bef.2005
B&S	Spinal	OAM Rigid Lumbar	I	33031	2018.01.11
B&S	Spinal	Occian® Back	I	41039	bef.2005
B&S	Spinal	One-Piece	I	41039	bef.2005
B&S	Spinal	Papoose®	I	41032	bef.2005
B&S	Spinal	Patriot®	I	41039	bef.2005
B&S	Spinal	Philadelphia® Adjustable	I	41039	2012.02.02
B&S	Spinal	Philadelphia® Halo	I	41039	bef.2005
B&S	Spinal	Philadelphia® Stabilizer	I	41453	bef.2005
B&S	Spinal	Philadelphia® Tracheotomy Collar	I	41039	2007.05.01
B&S	Spinal	ReSolve® Halo Vest	I	60367	2010.03.30
B&D	Spinal	Temporary Hernia Support	I	33031	bef.2006
B&S	Spinal	Universal Elastic Rib Belt	I	41042	bef.2006
B&S	Spinal	Velastic™ Plus	I	33031	2010.07.15
B&S	Wrist	Exoform® Wrist	I	41459	2005.02.01
B&S	Wrist	Exoform® Carpal Tunnel Wrist	I	41459	bef.2005
B&S	Wrist	Formfit® Wrist	I	41459	2016.02.05

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
B&S	Wrist	Formfit® Pro Wrist	I	41459	2018.06.01
B&S	Wrist	Formfit® Wrist & Forearm Universal	I	41459	2016.09.15
B&S	Wrist	Formfit® Wrist with Gel	I	41459	2016.02.05
B&S	Wrist	Formfit® Wrist Brace	I	41459	bef.2005
B&S	Wrist	Formfit® Wrist & Forearm	I	41459	2016.02.05
B&S	Wrist	Formfit® Wrist & Forearm Universal	I	41459	2016.09.15
B&S	Wrist	Formfit® Wrist & Forearm with Gel	I	41459	2016.02.05
B&S	Wrist	Formfit® Wrist Universal	I	41459	2016.09.15
B&S	Wrist	Neoprene/Elastic Wrist Thumb Brace	I	41459	bef.2005
B&S	Wrist	Simpla Wrist Support™	I	41459	bef.2005
B&S	Wrist	Spectra Wrist Brace	I	41459	2008.08.01
B&S	Wrist	Universal Wrist Brace	I	41459	2006.04.01
P	Arms	i-digits™ quantum	I		2018.07.13
P	Arms	i-digits™ access	I		2018.07.13
P	Arms	i-digits™ France	I		2018.07.13
P	Arms	i-limb® quantum	I		2018.07.13
P	Arms	i-limb ultra	I		2018.07.13
P	Arms	virtu-limb™	I		2018.07.13

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P	Arms	i-limb access	I		2018.07.13
P	Arms	livingskin	I		2018.07.13
P	Wrist	i-Limb Wrist	I	41090	2019.02.15
P	Components	4-Hole Adapters	I	61229	2003.10.30
P	Components	4-Hole Adapter with pyramid, rotatable	I	61229	2017.07.25
P	Components	4-Hole Adapter with pyramid receiver, rotatable	I	61229	2017.07.25
P	Components	Connection Plate	I	61229	2017.07.25
P	Components	Double Adapters	I	61229	bef.Nov.03
P	Components	Female Pylons Titanium, Waterproof	1	58823	2019.09.19
P	Components	Foot Adapters	I	61229	bef.Nov.03
P	Components	Height Adjustable Pylon	I	59001	2019.01.02
P	Components	Height Adjustable Pylon - Junior	I	59001	2019.01.02
P	Components	Junior Adapters	I	61229	bef.Nov.03
P	Components	Pylons	I	58823	bef.Nov.03
P	Components	Single Adapters	I	61229	bef.Nov.03
P	Components	Socket Adapters	I	61229	bef.Nov.03
P	Components	Special Adapters	I	61229	bef.Nov.03
P	Components	TF Unity Accessories	I	44595	2014.09.05

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Components	Torsion Shock Adapter	I	43569	2020.05.18
P	Components	Tube Clamps	I	59001	bef.Nov.03
P	Components	Tubes	I	58823	bef.Nov.03
P	Components	Unity Valve	I	44595	2012.12.05
P	Components	Unity® for Balance™ Foot S and Balance™ Foot S Torsion	I	44595	2020.02.24
P	Components	Unity® for Flex-Foot® Assure & Balance® J	I	44595	2015.05.12
P	Components	Unity® for Flex-Foot® Balance & K2 Sensation®	I	44595	2014.05.20
P	Components	Unity® for Pro-Flex®	I	44595	2015.12.01
P	Components	Unity® for Pro-Flex® LP	I	44595	2016.04.14
P	Components	Unity® for Pro-Flex® XC	I	44595	2016.01.13
P	Components	PROPRIO FOOT® W/UNITY	I	44595	2018.06.29
P	Components	Vacuum Valve	I	44595	2017.07.25
P	Feet	Allurion®	I	43569	bef.Aug.05
P	Feet	Balance™ Foot J	I	43569	2012.07.04
P	Feet	Balance™ Foot S	I	43569	2019.11.14
P	Feet	Balance™ Foot S Torsion	I	43569	2019.11.14
P	Feet	Flex-Foot Cheetah®	I	43569	bef.Aug.05
P	Feet	Cheetah® Junior	I	43569	2014.01.30

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Feet	Cheetah® Jump - Limited	I	43569	2019.03.13
P	Feet	Cheetah® Sprint - Limited	I	43569	2019.03.13
P	Feet	Cheetah® TF - Limited	I	43569	2019.04.16
P	Feet	Cheetah® Xceed	I	43569	2019.11.12
P	Feet	Cheetah® Xcel	I	43569	2019.11.12
P	Feet	Cheetah® Xpanse	I	43569	2019.11.12
P	Feet	Cheetah® Xplore	I	43569	2015.04.17
P	Feet	Cheetah® Xplore Junior	I	43569	2014.01.30
P	Feet	Cheetah® Xtreme	I	43569	2012.12.18
P	Feet	Cheetah® Xtend	I	43569	2012.12.18
P	Feet	Chopart	I	41533	2004.04.01
P	Feet	D/P Flexion™	I	43569	2014.12.23
P	Feet	Elation®	I	43569	2003.01.02
P	Feet	Flex-Foot® Assure	I	43569	2008.11.17
P	Feet	Flex-Foot® Balance	I	43571	2010.03.08
P	Feet	Flex-Foot® Junior	I	43569	2003.11.03
P	Feet	Flex-Run™ with Nike Sole	I	43569	2011.10.12
P	Feet	Flex-Symes	I	43569	2005.08.25
P	Feet	Flex-Walk	I	43569	bef.Aug.05

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P	Feet	Geriatric Foot	I	43569	bef. May 04
P	Feet	K2 Sensation®	I	43571	2013.07.05
P	Feet	LSF Calf Cosmesis	I	64737	2018.04.18
P	Feet	Nike Sole	I	64736	2015.05.15
P	Feet	Nike SoleX	I	64736	2020.04.30
P	Feet	Nike SoleX Attachment Kit	I	64736	2020.04.30
P	Feet	Nike Spike Pad	I	64736	2018.07.13
P	Feet	Ossur 100 Foot	I	43569	2006.07.05
P	Feet	Quick-Align™	I	43569	2012.03.13
P	Feet	Pivot	I	43569	2014.11.22
P	Feet	Pro-Flex®	I	43569	2015.11.14
P	Feet	Pro-Flex Pivot®	I	43569	2019.04.05
P	Feet	Pro-Flex™ Heel Height Adjustable - limited	I	43569	2016.09.16
P	Feet	Pro-Flex® LP	I	43569	2016.02.17
P	Feet	Pro-Flex® LP Align	I	43569	2018.04.18
P	Feet	Pro-Flex® LP Torsion	I	43569	2017.06.09
P	Feet	Pro-Flex® XC	I	43569	2015.12.23
P	Feet	Pro-Flex® XC Torsion	I	43569	2017.06.09

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Feet	Re-Flex (foot module)	I	43569	2010.11.08
P	Feet	Re-Flex Rotate™	I	43569	2010.11.08
P	Feet	Rotate Shock Kit	I	61229	2010.11.08
P	Feet	Re-Flex Shock™	I	43569	2011.05.10
P	Feet	Shock Kit	I	61229	2011.05.10
P	Feet	Re-Flex VSP LP	I	43569	bef.Aug.05
P	Feet	Talux®	I	43571	2010.05.10
P	Feet	Total Shock – Model #4400	I	61229	bef.Oct.01
P	Feet	Total Shock – Model #4410	I	61229	bef.Oct.01
P	Feet	Unity™	I	44595	2018.07.13
P	Feet	Vari-Flex®	I	43569	2009.05.20
P	Feet	Vari-Flex® Junior	I	43569	2014.01.30
P	Feet	Vari-Flex® Modular	I	43569	2012.11.08
P	Feet	LP Vari-Flex®	I	43569	2009.05.20
P	Feet	Foot Covers	I	43569	bef.2005
P	Knees	Balance™ Knee	I	43795	2011.05.27
P	Knees	Balance™ Knee Haiti Knee	I	58962	2017.07.04
P	Knees	Balance™ Knee Control	I	58962	2014.10.30
P	Knees	Balance™ Knee OFM1	I	43795	2017.06.02

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Knees	Balance™ Knee OFM2	I	58962	2017.06.02
P	Knees	Balance™ Knee OM8	I	43795	2017.06.02
P	Knees	Locking knee	I	58961	2012.09.01
P	Knees	LP Gaitmaster (JR)	I	58962	bef.Mar.02
P	Knees	Mauch® Knee	I	58962	2007.03.01
P	Knees	Mauch® Plus Knee	I	58962	2007.03.01
P	Knees	OH5 Knee	I	43795	2017.06.02
P	Knees	OH7 Knee	I	43795	2017.06.02
P	Knees	OHP3 Knee	I	43795	2017.06.02
P	Knees	OP2 Knee	I	43795	2017.06.02
P	Knees	OP2 Knee SE	I	43795	2017.07.04
P	Knees	OP4 Knee	I	58962	2017.06.02
P	Knees	OP5 Knee	I	43795	2017.06.02
P	Knees	Paso Knee	I	43795	2017.06.02
P	Knees	Safety Knee	I	58962	2014.03.20
P	Knees	SNJ cylinder	I	58962	bef.Oct.01
P	Knees	SNS cylinder	I	58962	bef.Oct.01
P	Knees	Total Knee® – Model #1100	I	43795	bef.Oct.01
P	Knees	Total Knee® – Model #1900	I	43795	bef.Oct.01

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Knees	Total Knee® – Model #2000	I	43795	bef.Oct.01
P	Knees	Total Knee® – Model #2100	I	43795	bef.Oct.01
P	Knees	Cheetah® Knee	I	43795	2016.04.29
P	Liners	4Seal Classic	I	41536	2017.06.02
P	Liners	4 Seal Senso	I	41536	2017.06.02
P	Liners	Akos	I	41536	2017.06.02
P	Liners	First	I	41536	2017.06.02
P	Liners	Genu Sleeve	I	44595	2017.06.02
P	Liners	Iceform® Liner Cushion	I	41536	2017.02.06
P	Liners	Iceform® Liner Locking	I	41536	2017.12.20
P	Liners	Iceform® Sleeve	I	44595	2017.06.02
P	Liners	Iceross Activa®	I	41536	2010.12.13
P	Liners	Iceross Comfort®	I	41536	bef.2000
P	Liners	Iceross Comfort Cushion®	I	41536	2010.01.19
P	Liners	Iceross Comfort Locking	I	41536	2018.07.13
P	Liners	Iceross Comfort® Wave Silken	I	41536	2012.05.25
P	Liners	Iceross Dermo®	I	41536	2000
P	Liners	Iceross Dermo® Junior	I	41536	2003.10.27
P	Liners	Iceross Dermo® Locking	I	41536	2018.07.13

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Liners	Iceross Dermo® Seal-In®	I	41536	2004.01.01
P	Liners	Iceross Dermo® Cushion	I	41536	2010.01.19
P	Liners	Iceross Dermo® Conical Wave	I	41536	2010.01.20
P	Liners	Iceross Dermo® Junior	I	41536	2018.07.13
P	Liners	Iceross Dermo® Uniform Cushion	I	41536	2018.07.13
P	Liners	Iceross Dermo® Uniform Locking	I	41536	2018.07.13
P	Liners	Iceross Dermo® Wave	I	41536	2006.03.06
P	Liners	Iceross® Distal Cup	I	41536	bef.Oct.05
P	Liners	Iceross® Original	I	41536	bef.2000
P	Liners	Aspire Locking Liner	I	41536	2013.07.05
P	Liners	Aspire TF Locking	I	41536	2021.01.26
P	Liners	Iceross® Liner Socks	I	41536	2013.09.23
P	Liners	Iceross® Post-Op	I	41536	2012.02.03
P	Liners	Iceross® Pads	I	41536	bef.Oct.05
P	Liners	Iceross Seal-In®	I	41536	2007.11.07
P	Liners	Iceross Seal-In® V	I	41536	2012.03.30
P	Liners	Iceross Seal-In® Wave	I	41536	2007.11.07
P	Liners	Iceross Seal-In® X	I	41536	2014.11.06
P	Liners	Iceross Seal-In® X-Classic	I	41536	2017.06.19

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Liners	Iceross Seal-In® X-Grip	I	41536	2017.06.19
P	Liners	Iceross Seal-In® X Locking	I	41536	2019.03.27
P	Liners	Iceross Seal-In® X TF	I	41536	2014.05.08
P	Liners	Iceross Seal-In® X5 TF	I	41536	2018.07.13
P	Liners	Iceross Seal-In® X-Volume	I	41536	2017.06.19
P	Liners	Iceross® Sleeve	I	44595	2009.03.31
P	Liners	Iceross® Sport	I	41536	2000.10.17
P	Liners	Iceross Stabilo® Junior	I	41536	2010.10.01
P	Liners	Iceross® Synergy	I	41536	2007.03.05
P	Liners	Iceross® Synergy Cushion	I	41536	2010.01.19
P	Liners	Iceross® Synergy Locking	I	41536	2018.07.13
P	Liners	Iceross® TF Seal-In	I	41536	2004.04.28
P	Liners	Iceross® Seal-In X5	I	41536	2008.09.15
P	Liners	Iceross® Transfemoral	I	41536	2000.11.02
P	Liners	Iceross® Upper-x	I	41536	bef.Oct.05
P	Liners	Protect 3C	I	41536	2017.06.02
P	Liners	Protect 3C Cushion	I	41536	2017.06.02
P	Liners	Relax 3C	I	41536	2017.06.02
P	Liners	Relax 3C Cushion	I	41536	2017.06.02

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Liners	Relax 6C	I	41536	2017.06.02
P	Liners	Relax 6C Cushion	I	41536	2017.06.02
P	Liners	Relax TF	I	41536	2017.06.02
P	Liners	Sensitive 3C	I	41536	2017.06.02
P	Liners	Sensitive 6C	I	41536	2017.06.02
P	Liners	Soft C	I	41536	2017.06.02
P	Liners	Volume Compensating Sleeve	I	44595	2017.06.02
P	Locks and Sleeves	Icelflex® Balance	I	44595	bef.Oct.01
P	Locks and Sleeves	Icelflex® Endurance	I	44595	bef.Oct.01
P	Locks and Sleeves	IceroSS® Sleeve	I	44595	2009.03.31
P	Locks and Sleeves	Icelock® 100 series	I	44595	bef. Jul.01
P	Locks and Sleeves	Icelock® 200 series	I	44595	bef. Jul.01
P	Locks and Sleeves	Icelock® 300 series	I	44595	bef. Jul.01
P	Locks and Sleeves	Icelock® 400 series	I	44595	bef. Jul.01
P	Locks and Sleeves	Icelock® 500 series	I	44595	bef. Jul.01
P	Locks and Sleeves	Icelock® 600 series	I	44595	bef. Jul.01
P	Locks and Sleeves	Icelock® 700 series	I	44595	2001.07.15

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Locks and Sleeves	Icelock® 562 Hybrid	I	44595	2019.03.27
P	Other	Comfort SCS	I	42811	2017.07.25
P	Other	Patient Activity Monitor (PAM)	I	36252	bef.Mar.04
P	Other	RELAX Night Care	I	42811	2017.07.25
P	Other	Össur® Rigid Dressing	I	35358	2012.01.14
P	Sockets	Pressure Pads	I	44595	bef.Oct.01
P	Sockets	Connect TF	I	41156	2019.09.02
P	Sockets	Direct Socket TF	I	41156	2019.10.10
P	Sockets	Direct Socket TT	I	41152	2018.10.25
P	Sockets - accessory	Direct Socket Tool Kit	I		2018.10.25

B&S	Spinal	Lil' Angel® Halo	Class I sterile, IIb	60367	Bef.2005
B&S	Spinal	ReSolve® Halo	Class I sterile, IIb	60367	bef.2005
B&S	Spinal	J-Tongs™	Class I sterile, IIb	46528	bef.2005
B&S	Spinal	Halo accessories	Class I, Class I sterile, IIb	60367	bef.2005

P	Accessories	Össur Logic	IIa	N/A – Accessory	2017.08.02
P	Feet	PROPRIO FOOT®	IIa		2018.06.29

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)
P	Knee	RHEOLOGIC™	IIa		2011.06.21
P	Knee	RHEO KNEE®	IIa		2017.08.02
P	Knee	RHEO KNEE® 3	IIa		2014.01.17
P	Knee	RHEO KNEE® II	IIa		2009.06.25
P	Knee	RHEO KNEE® XC	IIa		2016.04.19
P	Knee	POWER KNEE™	IIa		2010.11.30

Discontinued products

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)	Discontinued
B&S	Ankle	OSSUR Spring	I	36206	bef.2004	2004
B&S	Ankle	Equalizer® Walker	I	36206	bef.Jun.05	2016.09.15
B&S	Ankle	Equalizer® Air Walker	I	36206	bef.Jun.05	2016.09.15
B&S	Ankle	Exoform® Ankle Brace	I	36206	Mar.1998	2012.06.05
B&S	Ankle	Formfit® Night Splint 45	I	36206	2005.05.01	2016.08.16
B&S	Arm & Shoulder	Double Shoulder Brace	I	41465	bef.2006	2017.12.31
B&S	Arm & Shoulder	Mx Elevator Sling	I	13622	bef.2006	2013.12.31
B&S	Arm & Shoulder	Sub-Lux Cuff	I	41465	bef.2006	2017.12.31
B&S	Arm & Shoulder	Shoulder Abduction Wedge	I	41465	bef.2005	2017.12.31
B&S	Back	Formfit® Industrial Back Support	I	33031	bef.2006	2017
B&S	Back	Thera Back® Back Support	I	33031	bef.2006	2014.12.31
B&S	Back	Tri Back®	I	33031	bef.2005	2014.12.31
B&S	Casting & Splinting	Techform® I Cast Tape	I	43565	bef.2005	2010.08.01
B&S	Casting & Splinting	Techform® II Cast Tape	I	43565	2006.01.01	2010.10.01
B&S	Casting & Splinting	Techform® Standard Cast Tape	I	43565	2010.07.01	2014.12.31
B&S	Foot	OSSUR Footplate Tapered	I		bef.2004	2004
B&S	Elbow	Elbow Brace LP	I	41053	bef.2005	2013.11.15

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)	Discontinued
B&S	Elbow	Neoprene® Tennis Elbow Support	I	41053	bef.2005	2013.05.31
B&S	Hand	Abducted Wrist / Thumb Wrap	I	41459	bef.2006	2016.12.31
B&S	Hand	Formfit® Universal Thumb Brace	I		2013.01.09	2016.09.15
B&S	Hip	Hiptric™	I	36228	2009.02.01	2018.06.30
B&S	Knee	3DX®	I	41065	2005.06.10	2005
B&S	Knee	Deluxe Knee Immobilizer	I	12099	2006.01.01	2013.12.31
B&S	Knee	Edge	I	41065	Apr.07	2007.12.31
B&S	Knee	Morph®	I	41065	Apr.07	2008.07.01
B&S	Knee	MVP Contour Brace	I	41065	2011.04.18	2016.04.29
B&S	Knee	OAsys® CARTICARE	I	41065	bef. 2004	2017.12.31
B&S	Knee	Rehab	I	12099	bef. 2005	2018.11.20
B&S	Knee	Thermowrap™	I	41065	2005.01.01	2017.12.31
B&S	Knee	Trainer® OA	I	41065	2011.10.16	2016.02.06
B&S	Knee	Unloader® FIT	I	41065	2014.07.02	2018.05.10
B&S	Knee	Ultrawrap	I	41065	bef.2005	2015.05.13
B&S	Knee	Velsplint Knee Immobilizer	I	12099	bef.2005	2015.01.31
B&S	Other	Braun Frame	I		Jan.2010	2015.07.15
B&S	Other	Ossur Cosmetic Foam	I	58825	2004.08.01	bef.Jun.2008
B&S	Other	OSSUR Foam Plate	I		bef.Oct.03	bef.Jun.2008

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)	Discontinued
B&S	Other	OSSUR Silicone Padding Plate	I		bef.Oct.03	bef.jun.2008
B&S	Wrist	Formfit® Universal Wrist Brace	I		2013.01.09	2016.09.15
B&S	Wrist	Thermobrace™	I	41459	bef.2005	2017.12.31
B&S	Spinal	Assist 8 Extra™	I	33031	bef.2006	2018.03.01
B&S	Spinal	Atlas®	I	41039	bef.2005	2017.04.06
B&S	Spinal	EMT's Choice®	I	41039	bef.2005	2013.12.31
B&S	Spinal	Formfit® Lumbar	I	33031	2014.12.19	2016.11.07
B&S	Spinal	Miami Lumbar™	I	33031	2010.01.01	2019.09.30
P	Arms	i-limb Revolution	I		2018.07.13	2018.12.31
P	Components	ICON	I		bef.Oct.01	2003
P	Feet	Ceterus®	I	43569	2002.02.15	2012
P	Feet	Extensioner for Masterstep low profile	I		bef.Oct.01	2003.01
P	Feet	Flex-Seal	I	43569	bef.Oct.01	2007.06.14
P	Feet	Flex-Foot® Axia	I	43571	2005.10.01	2015.02.01
P	Feet	Flex-Sprint	I	43569	bef.Aug.05	2015.01.29
P	Feet	Low Profile Symes	I	43569	2005.08.25	2004.08.31
P	Feet	Masterstep foot with/without cosmetic cover	I	43569	bef.Oct.01	2003.01
P	Feet	Masterstep Pyramid Adapter	I	61229	bef.Oct.01	2003.01
P	Feet	Modular III	I	43569	bef.2000	2012.11.15

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)	Discontinued
P	Feet	Re-Flex VSP®	I	43569	bef.2000	2011.05.23
P	Feet	C-Sprint/Flex-Run	I	43569	bef.Aug.05	2012.05.31
P	Feet	Sure-Flex®	I	43569	bef.2003	2013.12.31
P	Feet	Total Concept – Model #8000	I		bef.Oct.01	2003.01
P	Feet	Total Concept – Model #8001	I		bef.Oct.01	2003.01
P	Feet	Total Concept Cosmetic Covers	I	58825	bef.Oct.01	2003.01
P	Feet	Cosmetic cover for Masterstep	I	58825	bef.Oct.01	2003.01
P	Feet	Ceterus®LP	I	43569	2003.09.21	2011.09.30
P	Feet	LP Rotate™	I	43569	2011.09.27	2017.11.03
P	Feet	LP Rotate™ with Unity	I	43569	2013.10.15	2017.11.03
P	Feet	Total Shock – Model #4500	I	61229	bef.Oct.01	2006.02
P	Feet	Vari-Flex®	I	43569	bef.2003	2011.09
P	Feet	Vari-Flex® LP	I	43569	2003.03.01	2012.06.21
P	Feet	Vari-Flex® XC	I	43569	2012.01.26	2016.12.19
P	Feet	Vari-Flex® XC Rotate	I	43569	2013.01.28	11.01.2017
P	Feet	Vari-Flex® XC with Unity	I	43569	2015.02.20	2016.12.19
P	Knees	Gaitmaster	I	58962	bef.Oct.01	2008.08
P	Knees	Mauch XG	I	58962	15.Apr.02	2008.06
P	Knees	MICROLITE	I	58962	bef.Oct.01	2002.02
P	Knees	Monolock Knee	I	58961	2017.06.02	2018.03.31

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)	Discontinued
P	Knees	Monolock Knee SE	I	58961	2017.07.04	2018.03.31
P	Knees	TKO 1500 Knee	I	58962	bef.Oct.01	2005.05
P	Liners	4 Seal Pure	I	41536	2017.06.02	2019.06.30
P	Liners	Iceross® Post-Op	I	41536	2002.07.04	2007.09.24
P	Liners	Iceross Comfort® Wave	I	41536	2010.05.04	2012.05.25
P	Liners	Iceross Cushion®	I	41536	2009.04.21	2010.01.19
P	Liners	Iceross Dermo® Std. Cushion	I	41536	2005.10.01	2010.12.31
P	Liners	Iceross Stabilo®	I	41536	2006.03.06	2008.02.07
P	Liners	Iceross Stabilo® Wave	I	41536	2006.09.01	2008.02.07
P	Liners	Iceross Stabilo Seal-In®	I	41536	2004.01.01	2010.12.31
P	Liners	TTm pop	I	41536	2017.06.02	2019.07.12
P	Liners	TFm pop	I	41536	2017.06.02	2019.07.12
P	Other	Ossur Cosmetic Glove, pvc	I		bef. May 04	2006.09
P	Other	Ossur Cosmetic Glove, silicone	I		bef. May 04	2006.09
P	Other	Ossur Cosmetic Hand, reinforced	I		bef.Jan.04	2006.09
P	Other	Ossur Cosmetic Hand, standard reinforced	I		bef.Jan.04	2006.09
P	Other	Ossur Cosmetic Hand, super reinforced	I		bef.Jan.04	2006.09
P	Other	Ossur TT FlexSkin®	I		2004.06.01	2008.01
P	Other	RELAX Pants	I	33435	2017.07.25	2018.07.30
P	Other	RELAX SCS	I	42811	2017.07.25	2019.02.28

		Product	Classification	GMDN code	Valid from date (yyyy/mm/dd)	Discontinued
P	Sockets	IceX® Socket System	I	44595	bef.Oct.01	2008.06
P	Sockets	Modular Socket System	I	44595	2007.11.19	2018.10.29
P	Feet	PROPRIO FOOT™ (prelaunch 26.06.06)	Ila		2009.04.06	2010
P	Feet	PROPRIO FOOT™	Ila		2010.08.06	2011
P	Feet	SYMBIONIC™ Leg	Ila		2012.03.28	2014
P	Feet	SYMBIONIC™ Leg 3	Ila		2014.06.11	2018.07.31
P	Knee	RHEO KNEE®	Ila		2004.12.29	2009
P	Knee	RHEO KNEE® 3.5	Ila		2017.05.31	2017.08.02

Abbreviations:

- P: Prosthetics
- B&S: Braces and supports
- OTS: Off the shelf
- LP: Low profile
- AFO: Ankle Foot Orthosis