

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

Össur runs a quality system according to ISO 9001:2008 and ISO 13485:2012

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

This declaration is valid from June the 10<sup>th</sup> 2005.

It was last updated June 8<sup>th</sup> 2017.



Jóhanna Valdimarsdóttir

Quality Assurance Director

ÖSSUR

		Product	Valid from date	Discontinued	Classification
<b>B&amp;S</b>	Ankle	<b>AFO Dynamic</b>	May.2005		I
<b>B&amp;S</b>	Ankle	<b>AFO Light</b>	May.2005		I
<b>B&amp;S</b>	Ankle	<b>Airform® Ankle Stirrup</b>	bef.2005		I
<b>B&amp;S</b>	Ankle	<b>Airform® Universal Inflatable Stirrup Ankle Brace</b>	Jul.2005		I
<b>B&amp;S</b>	Ankle	<b>Equalizer® Walker</b>	bef.Jun.05	15.9.2016	I
<b>B&amp;S</b>	Ankle	<b>Equalizer® Air Walker</b>	bef.Jun.05	15.9.2016	I
<b>B&amp;S</b>	Ankle	<b>Exoform® Ankle Brace</b>	Mar.1998	5.June.2012	I
<b>B&amp;S</b>	Ankle	<b>Foam Ankle Stirrup</b>	bef.2005		I
<b>B&amp;S</b>	Ankle	<b>Foot-Up™</b>	bef.2005		I
<b>B&amp;S</b>	Ankle	<b>Form Fit® Ankle</b>	5.2.2016		I
<b>B&amp;S</b>	Ankle	<b>Form Fit® Ankle Brace</b>	11.Feb.11		I
<b>B&amp;S</b>	Ankle	<b>Form Fit® Ankle with Figure 8</b>	5.2.2016		I
<b>B&amp;S</b>	Ankle	<b>Form Fit® Ankle with Speedlace</b>	5.2.2016		I
<b>B&amp;S</b>	Ankle	<b>Form Fit® Foam Ankle Brace</b>	Jan.1996		I
<b>B&amp;S</b>	Ankle	<b>Form Fit® Night Splint</b>	29.March.10		I
<b>B&amp;S</b>	Ankle	<b>Form Fit® Night Splint 45</b>	25.June.10		I
<b>B&amp;S</b>	Ankle	<b>GameDay™ Ankle Brace</b>	14.Nov.07		I
<b>B&amp;S</b>	Ankle	<b>Rebound® Ankle Brace</b>	1.Jan.10		I

		<b>Product</b>	<b>Valid from date</b>	<b>Discontinued</b>	<b>Classification</b>
<b>B&amp;S</b>	Ankle	<b>Rebound Air® Walker</b>	25.May.10		I
<b>B&amp;S</b>	Ankle	<b>Rebound Air® Walker Euro</b>	20.Jun.12		I
<b>B&amp;S</b>	Ankle	<b>Rebound Air® Walker Low Top</b>	28.Oct.10		I
<b>B&amp;S</b>	Ankle	<b>Rebound Foot-Up®</b>	25.Jan.17		I
<b>B&amp;S</b>	Arm	<b>Bergschultz Universal Arm Sling</b>	bef.2005		I
<b>B&amp;S</b>	Arm	<b>Innovator X® Post-Op Elbow Brace</b>	1.Nov.06		I
<b>B&amp;S</b>	Arm	<b>Premium Contact Closure Arm Sling</b>	bef.2005		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Double Shoulder Brace</b>	bef.2006		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Form Fit® Shoulder Brace</b>	5.2.2016		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Form Fit® Shoulder Brace with Abduction</b>	5.2.2016		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Form Fit® Shoulder Brace with External Rotation</b>	5.2.2016		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Form Fit® Tennis Elbow</b>	2.Jan.12		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Monitor Arm Sling</b>	bef.2006		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Mx Elevator Sling</b>	bef.2006		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Premium Shoulder Immobilizer</b>	bef.2005		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Shoulder Abduction Wedge</b>	bef.2005		I

		<b>Product</b>	<b>Valid from date</b>	<b>Discontinued</b>	<b>Classification</b>
<b>B&amp;S</b>	Arm & Shoulder	<b>Smartsling®</b>	bef.2005		I
<b>B&amp;S</b>	Arm & Shoulder	<b>Sub-Lux Cuff</b>	bef.2006		I
<b>B&amp;S</b>	Back	<b>Airform® Inflatable Back Support</b>	bef.2005		I
<b>B&amp;S</b>	Back	<b>Form Fit® Advance Back</b>	bef.2005		I
<b>B&amp;S</b>	Back	<b>Form Fit® Industrial Back Support</b>	bef.2006		I
<b>B&amp;S</b>	Back	<b>Thera Back® Back Support</b>	bef.2006		I
<b>B&amp;S</b>	Back	<b>Tri Back®</b>	bef.2005		I
<b>B&amp;S</b>	Casting & Splinting	<b>Techform® I Cast Tape</b>	bef.2005	1.Aug. 2010	I
<b>B&amp;S</b>	Casting & Splinting	<b>Techform® II Cast Tape</b>	1.Jan.2006	1. Oct. 2010	I
<b>B&amp;S</b>	Casting & Splinting	<b>Techform® Ortho-Roll</b>	1.Jan.2006		I
<b>B&amp;S</b>	Casting & Splinting	<b>Techform® Pre-Cut Splints</b>	1.Jan.2006		I
<b>B&amp;S</b>	Casting & Splinting	<b>Techform® Premium Cast Tape</b>	1.Jul.2010		I
<b>B&amp;S</b>	Casting & Splinting	<b>Techform® Standard Cast Tape</b>	1.Jul.2010		I
<b>B&amp;S</b>	Clavicle	<b>Figure 8 Clavicle Splint</b>	bef.2005		I
<b>B&amp;S</b>	Clavicle	<b>Front Closure Clavicle Support</b>	bef.2006		I
<b>B&amp;S</b>	Clavicle	<b>Universal Elastic Rib Belt</b>	bef.2006		I
<b>B&amp;S</b>	Elbow	<b>Airform® Tennis elbow</b>	bef.2005		I

		Product	Valid from date	Discontinued	Classification
B&S	Elbow	Elbow Brace LP	bef.2005		I
B&S	Elbow	Neoprene® Tennis Elbow Support	bef.2005		I
B&S	Hand	Abducted Wrist / Thumb Wrap	bef.2006		I
B&S	Hand	Elastic Thumb Spica	bef.2005		I
B&S	Hand	Form Fit® Thumb Spica	bef.2005		I
B&S	Hand	Form Fit® Thumb Spica Universal	15.9.2016		I
B&S	Hand	Form Fit® Thumb Spica with Gel	5.2.2016		I
B&S	Hand	Form Fit® Universal Thumb Brace	9.Jan.2013	15.9.2016	I
B&S	Hand	Unloader® Thumb Day	3.Dec.14		I
B&S	Hand	Unloader® Thumb Night	3.Dec.14		I
B&S	Hand	Universal Thumb Spica	1.Apr.07		I
B&S	Hip	Hiptric™	1.Feb.09		I
B&S	Hip	Unloader® Hip	27.Jun.13		I
B&S	Foot	Airform Night Splint®	bef.2005		I
B&S	Foot	AFO Leaf Spring	bef.2005		I
B&S	Foot	Dorsal Night Splint	Aug.08		I
B&S	Foot	DH Offloading Walker™	bef.2005		I
B&S	Foot	Form Fit® Night Splint Posterior	7.2.2017		I
B&S	Foot	Rebound Diabetic Walker	2.Apr.14		I

		Product	Valid from date	Discontinued	Classification
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B&S	Foot	ROM Walker	bef.2005		I
B&S	Knee	Deluxe Knee Immobilizer	Jan.06		I
B&S	Knee	CTi® Custom	Apr.07		I
B&S	Knee	CTi® OTS	Apr.07		I
B&S	Knee	CTi® Vapor	Feb.2008		I
B&S	Knee	Extreme	bef.2005		I
B&S	Knee	Exoform® Knee Immobilizer	bef.2005		I
B&S	Knee	Flex™	Apr.07		I
B&S	Knee	Form Fit® 16" Post Op Knee Full Foam	8.6.2017		I
B&S	Knee	Form Fit® 24" Post Op Knee Full & Cool Foam	8.6.2017		I
B&S	Knee	Form Fit® 28" Post Op Knee Full & Cool Foam	8.6.2017		I
B&S	Knee	Form Fit® Knee	26.May.11		I
B&S	Knee	Form Fit® Knee Hinged Lateral J	5.2.2016		I
B&S	Knee	Form Fit® Knee Hinged Sleeve	5.2.2016		I
B&S	Knee	Form Fit® Knee Hinged Wrap	5.2.2016		I
B&S	Knee	Form Fit® Knee Immobilizer Universal	7.2.2017		I
B&S	Knee	Form Fit® Knee MCL	20.12.2016		I
B&S	Knee	Form Fit® Knee ROM 12" Sleeve	15.9.2016		I

		Product	Valid from date	Discontinued	Classification
<b>B&amp;S</b>	Knee	<b>Form Fit® Knee ROM 16" Sleeve</b>	15.9.2016		I
<b>B&amp;S</b>	Knee	<b>Form Fit® Knee ROM 12" Wrap</b>	15.9.2016		I
<b>B&amp;S</b>	Knee	<b>Form Fit® Knee ROM 16" Wrap</b>	15.9.2016		I
<b>B&amp;S</b>	Knee	<b>Form Fit® Neoprene Hinged Knee Support</b>	bef.2005	15.9.2016	I
<b>B&amp;S</b>	Knee	<b>Form Fit® OA Wraparound</b>	26.May.15		I
<b>B&amp;S</b>	Knee	<b>Paradigm® OTS</b>	10.Jun.05		I
<b>B&amp;S</b>	Knee	<b>Patella Cup</b>	31.Des.13		I
<b>B&amp;S</b>	Knee	<b>PCL Pad Accessory kit</b>	14.Jan.15		I
<b>B&amp;S</b>	Knee	<b>PFOA</b>	22.Oct.14		I
<b>B&amp;S</b>	Knee	<b>Rebound® DUAL</b>	5. August 15		I
<b>B&amp;S</b>	Knee	<b>Rebound® Knee Brace</b>	28. Jul. 11		I
<b>B&amp;S</b>	Knee	<b>Rebound® ACL</b>	9. Sept. 14		I
<b>B&amp;S</b>	Knee	<b>Rebound® PCL</b>	22. Oct. 14		I
<b>B&amp;S</b>	Knee	<b>Rebound® Cartilage</b>	28. Jun. 13		I
<b>B&amp;S</b>	Knee	<b>Rebound® Cartilage Custom</b>	5. Marz 15		I
<b>B&amp;S</b>	Knee	<b>Rebound® Post-Op Knee</b>	23.3.2017		I
<b>B&amp;S</b>	Knee	<b>Thermowrap™</b>	Jan. 05		I
<b>B&amp;S</b>	Knee	<b>Trainer®</b>	10. Jun. 05		I

		Product	Valid from date	Discontinued	Classification
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B&S	Knee	Trainer® OA	16. Nov. 2011		I
B&S	Knee	Innovator®	Bef. 2006		I
B&S	Knee	Innovator DLX®	9. Oct. 06		I
B&S	Knee	Innovator DLX® +	25. Oct. 12		I
B&S	Knee	MVP Contour Brace	18. Apr. 11	29. Apr. 16	I
B&S	Knee	Neoprene Wraparound Hinged Knee Support	bef. 2005		I
B&S	Knee	Rehab	bef. 2005		I
B&S	Knee	OAsys® CARTICARE	bef. 2004		I
B&S	Knee	Universal 3-Panel Knee Immobilizer	bef. 2005		I
B&S	Knee	Unloader® ADJ	bef. 2005		I
B&S	Knee	Unloader® Custom	bef. 2005		I
B&S	Knee	Unloader® Express	bef. 2005		I
B&S	Knee	Unloader® FIT	2.Jul.14		I
B&S	Knee	Unloader® Lite	bef.2005		I
B&S	Knee	Unloader® One Lite	15.2.17		I
B&S	Knee	Unloader® One OTS	19.Oct.10		I
B&S	Knee	Unloader® One Custom	19.Oct.10		I
B&S	Knee	Unloader® One Plus	20.June.11		I



		<b>Product</b>	<b>Valid from date</b>	<b>Discontinued</b>	<b>Classification</b>
<b>B&amp;S</b>	Knee	<b>Unloader® PF</b>	10. May 16		I
<b>B&amp;S</b>	Knee	<b>Unloader® Select</b>	bef.2005		I
<b>B&amp;S</b>	Knee	<b>Unloader Spirit®</b>	bef.2005		I
<b>B&amp;S</b>	Knee	<b>Unloader One® SmartDosing</b>	5.Sept.12		I
<b>B&amp;S</b>	Knee	<b>Unloader® XT</b>	bef.2005		I
<b>B&amp;S</b>	Knee	<b>Undersleeve</b>	8.April.13		I
<b>B&amp;S</b>	Knee	<b>Ultrawrap</b>	bef.2005		I
<b>B&amp;S</b>	Knee	<b>Velsplint Knee Immobilizer</b>	bef.2005		I
<b>B&amp;S</b>	Other	<b>Braun Frame</b>	Jan.2010		I
<b>B&amp;S</b>	Other	<b>Canvas Rocker Bottom Cast Shoes</b>	bef.2006		I
<b>B&amp;S</b>	Other	<b>Insoles</b>	bef.2005		I
<b>B&amp;S</b>	Other	<b>DH Offloading Post-Op Shoe</b>	Jan.2010		I
<b>B&amp;S</b>	Other	<b>Thomas Splint</b>	20.Oct.2003		I
<b>B&amp;S</b>	Other	<b>Constant Force Caliper</b>	27.Jun.2013		I
<b>B&amp;S</b>	Spinal	<b>Assist 8 Extra™</b>	bef.2006		I
<b>B&amp;S</b>	Spinal	<b>Atlas®</b>	bef.2005		I
<b>B&amp;S</b>	Spinal	<b>Dual Maternity Belt</b>	bef.2006		I
<b>B&amp;S</b>	Spinal	<b>EMT's Choice®</b>	bef.2005		I
<b>B&amp;S</b>	Spinal	<b>Foam Cervical Collar</b>	Jan.2009		I

		Product	Valid from date	Discontinued	Classification
B&S	Spinal	Form Fit® Back Support	7.Feb.17		I
B&S	Spinal	Form Fit® Back Support Air	7.Feb.17		I
B&S	Spinal	Form Fit® Lumbar	19.Dec.14		I
B&S	Spinal	JTO Thoracic Extension	bef.2005		I
B&S	Spinal	Hip-y	jan.2006		I
B&S	Spinal	Miami J®	bef.2005		I
B&S	Spinal	Miami J® Advanced	14.Jul.10		I
B&S	Spinal	Miami Jr®	bef.2005		I
B&S	Spinal	Miami LSO™	22.Feb.2017		I
B&S	Spinal	Miami Lumbar™ TLSO	25.Mar.2010		I
B&S	Spinal	Miami Lumbar™	1.Jan.2010		I
B&S	Spinal	Miami Lumber™ Posteo	9.Nov.12		I
B&S	Spinal	Miami Lumbar™ Slim	17.May.2011		I
B&S	Spinal	NecLoc®	bef.2005		I
B&S	Spinal	NecLoc® Kids	bef.2005		I
B&S	Spinal	Occian® Back	bef.2005		I
B&S	Spinal	One-Piece	bef.2005		I
B&S	Spinal	Papoose®	bef.2005		I
B&S	Spinal	Patriot®	bef.2005		I

		<b>Product</b>	<b>Valid from date</b>	<b>Discontinued</b>	<b>Classification</b>
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<b>B&amp;S</b>	Spinal	<b>Philadelphia® Adjustable</b>	2.Feb.12		I
<b>B&amp;S</b>	Spinal	<b>Philadelphia® Halo</b>	bef.2005		I
<b>B&amp;S</b>	Spinal	<b>Philadelphia® Stabilizer</b>	bef.2005		I
<b>B&amp;S</b>	Spinal	<b>Philadelphia® Tracheotomy Collar</b>	May.2007		I
<b>B&amp;S</b>	Spinal	<b>Rebound® Hip</b>	11.Jan.2013		I
<b>B&amp;S</b>	Spinal	<b>ReSolve® Halo Vest</b>	30.mars.10		I
<b>B&amp;D</b>	Spinal	<b>Temporary Hernia Support</b>	bef.2006		I
<b>B&amp;S</b>	Spinal	<b>Universal Abdominal Binder</b>	bef.2006		I
<b>B&amp;S</b>	Spinal	<b>Velastic™ Plus</b>	15.July.10		I
<b>B&amp;S</b>	Wrist	<b>Carp-X™</b>	bef.2005		I
<b>B&amp;S</b>	Wrist	<b>Exoform® Wrist</b>	1.Feb.05		I
<b>B&amp;S</b>	Wrist	<b>Exoform® Carpal Tunnel Wrist</b>	bef.2005		I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Universal Wrist Brace</b>	9.Jan.2013	15.9.2016	I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist</b>	5.2.2016		I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist &amp; Forearm Universal</b>	15.9.2016		I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist with Gel</b>	5.2.2016		I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist Brace</b>	bef.2005		I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist &amp; Forearm</b>	5.2.2016		I

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<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist &amp; Forearm Universal</b>	15.9.2016		I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist &amp; Forearm with Gel</b>	5.2.2016		I
<b>B&amp;S</b>	Wrist	<b>Form Fit® Wrist Universal</b>	15.9.2016		I
<b>B&amp;S</b>	Wrist	<b>Neoprene/Elastic Wrist Thumb Brace</b>	bef.2005		I
<b>B&amp;S</b>	Wrist	<b>Simpla Wrist Support™</b>	bef.2005		I
<b>B&amp;S</b>	Wrist	<b>Spectra Wrist Brace</b>	1.Aug.08		I
<b>B&amp;S</b>	Wrist	<b>Thermobrace™</b>	bef.2005		I
<b>B&amp;S</b>	Wrist	<b>Universal Wrist Brace</b>	April.2006		I

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<b>B&amp;S</b>	Spinal	<b>Lil' Angel® Halo</b>	bef.2005		Class I sterile, IIa, IIb
<b>B&amp;S</b>	Spinal	<b>ReSolve® Halo</b>	bef.2005		Class I sterile, IIa, IIb
<b>B&amp;S</b>	Spinal	<b>J-Tongs™</b>	bef.2005		Class I sterile, IIa, IIb
<b>B&amp;S</b>	Spinal	<b>Halo accessories</b>	bef.2005		Class I sterile, IIa, IIb

#### Discontinued products

<b>B&amp;S</b>	Ankle	<b>OSSUR Spring</b>	bef.2004	2004	I
<b>B&amp;S</b>	Foot	<b>OSSUR Footplate Tapered</b>	bef.2004	2004	I
<b>B&amp;S</b>	Knee	<b>Edge</b>	Apr.07	31.Dec.2007	I
<b>B&amp;S</b>	Knee	<b>3DX®</b>	10.Jun.05	2005	I
<b>B&amp;S</b>	Knee	<b>Morph®</b>	Apr.07	1.Jul.2008	I
<b>B&amp;S</b>	Other	<b>Ossur Cosmetic Foam</b>	1.Aug.04	bef.Jun.2008	I
<b>B&amp;S</b>	Other	<b>OSSUR Foam Plate</b>	bef.Oct.03	bef.Jun.2008	I
<b>B&amp;S</b>	Other	<b>OSSUR Silicone Padding Plate</b>	bef.Oct.03	bef.jun.2008	I

#### Abbreviations:

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

		<b>Product</b>	<b>Valid from date</b>	<b>Discontinued</b>	<b>Classification</b>
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