



Reykjavík, 3.4.2017

Tilvísun: 8.1.11 / Málsnúmer: 2017040010

Free Sale Certificate

Icelandic Medicines Agency certifies herewith, that the following medical devices meet the legal requirements set out in the Icelandic law on Medical Devices No. 16/2001 as well as in Medical Devices Directive 93/42/EEC:

B&S	Ankle	AFO Dynamic
B&S	Ankle	AFO Light
B&S	Ankle	Airform® Ankle Stirrup
B&S	Ankle	Airform® Universal Inflatable Stirrup Ankle Brace
B&S	Ankle	Foam Ankle Stirrup
B&S	Ankle	Foot-Up™
B&S	Ankle	Form Fit® Ankle
B&S	Ankle	Form Fit® Ankle Brace
B&S	Ankle	Form Fit® Ankle with Figure 8
B&S	Ankle	Form Fit® Ankle with Speedlace
B&S	Ankle	Form Fit® Foam Ankle Brace
B&S	Ankle	Form Fit® Night Splint
B&S	Ankle	Form Fit® Night Splint 45
B&S	Ankle	Form Fit®
B&S	Ankle	Form Fit® Walker Low Top
B&S	Ankle	Form Fit® Walker Air
B&S	Ankle	Form Fit® Walker Air Low Top
B&S	Ankle	GameDay™ Ankle Brace
B&S	Ankle	Rebound® Ankle Brace
B&S	Ankle	Rebound Air® Walker Euro



B&S	Ankle	Rebound Air® Walker Low Top
B&S	Ankle	Rebound Foot-Up®
B&S	Arm	Bergschultz Universal Arm Sling
B&S	Arm	Innovator X® Post-Op Elbow Brace
B&S	Arm	Premium Contact Closure Arm Sling
B&S	Arm & Shoulder	Double Shoulder Brace
B&S	Arm & Shoulder	Form Fit® Shoulder Brace
B&S	Arm & Shoulder	Form Fit® Shoulder Brace with Abduction
B&S	Arm & Shoulder	Form Fit® Shoulder Brace with External Rotation
B&S	Arm & Shoulder	Form Fit® Tennis Elbow
B&S	Arm & Shoulder	Monitor Arm Sling
B&S	Arm & Shoulder	Mx Elevator Sling
B&S	Arm & Shoulder	Premium Shoulder Immobilizer
B&S	Arm & Shoulder	Shoulder Abduction Wedge
B&S	Arm & Shoulder	Smartsling®
B&S	Arm & Shoulder	Sub-Lux Cuff
B&S	Back	Airform® Inflatable Back Support
B&S	Back	Form Fit® Advance Back
B&S	Back	Form Fit® Industrial Back Support
B&S	Back	Thera Back® Back Support
B&S	Back	Tri Back®
B&S	Casting & Splinting	Techform® Ortho-Roll
B&S	Casting & Splinting	Techform® Pre-Cut Splints
B&S	Casting & Splinting	Techform® Premium Cast Tape
B&S	Casting & Splinting	Techform® Standard Cast Tape
B&S	Clavicle	Figure 8 Clavicle Splint
B&S	Clavicle	Front Closure Clavicle Support
B&S	Clavicle	Universal Elastic Rib Belt
B&S	Elbow	Airform® Tennis elbow
B&S	Elbow	Elbow Brace LP
B&S	Elbow	Neoprene® Tennis Elbow Support
B&S	Hand	Abducted Wrist / Thumb Wrap



B&S	Hand	Elastic Thumb Spica
B&S	Hand	Form Fit® Thumb Spica
B&S	Hand	Form Fit® Thumb Spica Universal
B&S	Hand	Form Fit® Thumb Spica with Gel
B&S	Hand	Unloader® Thumb Day
B&S	Hand	Unloader® Thumb Night
B&S	Hand	Universal Thumb Spica
B&S	Hip	Hiptric™
B&S	Hip	Unloader® Hip
B&S	Foot	Airform Night Splint®
B&S	Foot	AFO Leaf Spring
B&S	Foot	Dorsal Night Splint
B&S	Foot	DH Offloading Walker™
B&S	Foot	Form Fit® Night Splint Posterior
B&S	Foot	Rebound Diabetic Walker
B&S	Foot	ROM Walker
B&S	Knee	Deluixe Knee Immobilizer
B&S	Knee	CTi® Custom
B&S	Knee	CTi® OTS
B&S	Knee	CTi® Vapor
B&S	Knee	Extreme
B&S	Knee	Exoform® Knee Immobilizer
B&S	Knee	Flex™
B&S	Knee	Form Fit® Knee Hinged Lateral J
B&S	Knee	Form Fit® Knee Hinged Sleeve
B&S	Knee	Form Fit® Knee Hinged Wrap
B&S	Knee	Form Fit® Knee Immobilizer Universal
B&S	Knee	Form Fit® Knee MCL
B&S	Knee	Form Fit® Knee ROM 12" Sleeve
B&S	Knee	Form Fit® Knee ROM 16" Sleeve
B&S	Knee	Form Fit® Knee ROM 12" Wrap
B&S	Knee	Form Fit® Knee ROM 16" Wrap



B&S	Knee	Form Fit® OA Wraparound
B&S	Knee	Paradigm® OTS
B&S	Knee	Patella Cup
B&S	Knee	PCL Pad Accessory kit
B&S	Knee	PFOA
B&S	Knee	Rebound® DUAL
B&S	Knee	Rebound® Knee Brace
B&S	Knee	Rebound® ACL
B&S	Knee	Rebound® PCL
B&S	Knee	Rebound® Cartilage
B&S	Knee	Rebound® Cartilage Custom
B&S	Knee	Rebound® Post-Op Knee
B&S	Knee	Thermowrap™
B&S	Knee	Trainer®
B&S	Knee	Trainer® OA
B&S	Knee	Innovator®
B&S	Knee	Innovator DLX®
B&S	Knee	Innovator DLX® +
B&S	Knee	Neoprene Wraparound Hinged Knee Support
B&S	Knee	Rehab
B&S	Knee	OAsys® CARTICARE
B&S	Knee	Universal 3-Panel Knee Immobilizer
B&S	Knee	Unloader® ADJ
B&S	Knee	Unloader® Custom
B&S	Knee	Unloader® Express
B&S	Knee	Unloader® FIT
B&S	Knee	Unloader® Lite
B&S	Knee	Unloader® One Lite
B&S	Knee	Unloader® One OTS
B&S	Knee	Unloader® One Custom
B&S	Knee	Unloader® One Plus
B&S	Knee	Unloader® One SmartDosing



B&S	Knee	Unloader® PF
B&S	Knee	Unloader® Select
B&S	Knee	Unloader Spirit®
B&S	Knee	Unloader® XT
B&S	Knee	Undersleeve
B&S	Knee	Ultrawrap
B&S	Knee	Velsplint Knee Immobilizer
B&S	Other	Braun Frame
B&S	Other	Canvas Rocker Bottom Cast Shoes
B&S	Other	Insoles
B&S	Other	DH Offloading Post-Op Shoe
B&S	Other	Thomas Splint
B&S	Other	Constant Force Caliper
B&S	Spinal	Assist 8 Extra™
B&S	Spinal	Atlas®
B&S	Spinal	Dual Maternity Belt
B&S	Spinal	EMT's Choice®
B&S	Spinal	Foam Cervical Collar
B&S	Spinal	Form Fit® Back Support
B&S	Spinal	Form Fit® Back Support Air
B&S	Spinal	Form Fit® Lumbar
B&S	Spinal	JTO Thoracic Extension
B&S	Spinal	Hip-y
B&S	Spinal	Miami J®
B&S	Spinal	Miami J® Advanced
B&S	Spinal	Miami Jr®
B&S	Spinal	Miami LSO™
B&S	Spinal	Miami Lumbar™ TLSO
B&S	Spinal	Miami Lumbar™
B&S	Spinal	Miami Lumbar™ Posteo
B&S	Spinal	Miami Lumbar™ Slim
B&S	Spinal	NecLoc®



B&S	Spinal	NecLoc® Kids
B&S	Spinal	Occian® Back
B&S	Spinal	One-Piece
B&S	Spinal	Papoose®
B&S	Spinal	Patriot®
B&S	Spinal	Philadelphia® Adjustable
B&S	Spinal	Philadelphia® Halo
B&S	Spinal	Philadelphia® Stabilizer
B&S	Spinal	Philadelphia® Tracheotomy Collar
B&S	Spinal	Rebound® Hip
B&S	Spinal	ReSolve® Halo Vest
B&D	Spinal	Temporary Hernia Support
B&S	Spinal	Universal Abdominal Binder
B&S	Spinal	Velastic™ Plus
B&S	Wrist	Carp-X™
B&S	Wrist	Exoform® Wrist
B&S	Wrist	Exoform® Carpal Tunnel Wrist
B&S	Wrist	Form Fit® Wrist
B&S	Wrist	Form Fit® Wrist & Forearm Universal
B&S	Wrist	Form Fit® Wrist with Gel
B&S	Wrist	Form Fit® Wrist Brace
B&S	Wrist	Form Fit® Wrist & Forearm
B&S	Wrist	Form Fit® Wrist & Forearm Universal
B&S	Wrist	Form Fit® Wrist & Forearm with Gel
B&S	Wrist	Form Fit® Wrist Universal
B&S	Wrist	Neoprene/Elastic Wrist Thumb Brace
B&S	Wrist	Simpla Wrist Support™
B&S	Wrist	Spectra Wrist Brace
B&S	Wrist	Thermobrace™
B&S	Wrist	Universal Wrist Brace
P Components		4-Hole Adapters
P Components		Double Adapters



P Components Foot Adapters
P Components Junior Adapters
P Components Pylons
P Components Single Adapters
P Components Socket Adapters
P Components Special Adapters
P Components TF Unity Accessories
P Components Tube Clamps
P Components Tubes
P Components Unity Valve
P Components Unity® for Flex-Foot® Assure & Balance® J
P Components Unity® for Flex-Foot® Balance & K2 Sensation®
P Components Unity® for Pro-Flex®
P Components Unity® for Pro-Flex® LP
P Components Unity® for Pro-Flex® XC
P Feet Allurion®
P Feet Balance™ Foot J
P Feet Ceterus®
P Feet Cheetah®
P Feet Cheetah® Junior
P Feet Cheetah® Xplore
P Feet Cheetah® Xplore Junior
P Feet Cheetah® Xtreme
P Feet Cheetah® Xtend
P Feet Chopart
P Feet D/P Flexion™
P Feet Elation®
P Feet Flex-Foot® Axia
P Feet Flex-Foot® Assure
P Feet Flex-Foot® Assure
P Feet Flex-Foot® Balance
P Feet Flex-Foot® Junior



P Feet Flex-Run™ with Nike Sole
P Feet Flex-Sprint
P Feet Flex-Symes
P Feet Flex-Walk
P Feet FST Footcover
P Feet Geriatric Foot
P Feet K2 Sensation®
P Feet LP Rotate™
P Feet LP Rotate™ with Unity
P Feet Nike Sole Junior
P Feet Ossur 100 Foot
P Feet Quick-Align™
P Feet Pivot
P Feet Pro-Flex™
P Feet Pro-Flex® LP
P Feet Pro-Flex™ XC
P Feet Re-Flex (foot module)
P Feet Re-Flex Rotate™
P Feet Re-Flex Rotate™
P Feet Rotate Shock Kit
P Feet Re-Flex Shock™
P Feet Shock Kit
P Feet Re-Flex VSP LP
P Feet Talux®
P Feet Total Shock – Model #4400
P Feet Total Shock – Model #4410
P Feet Vari-Flex®
P Feet Vari-Flex® Junior
P Feet Vari-Flex® LP with Unity
P Feet Vari-Flex® Modular
P Feet Vari-Flex® with Unity
P Feet Vari-Flex® XC



P Feet Vari-Flex® XC Rotate
P Feet Vari-Flex® XC with Unity
P Feet LP Vari-Flex®
P Feet Foot Covers (Flex-Foot)
P Knees Balance™ Knee
P Knees Balance™ Knee Control
P Knees Locking knee
P Knees LP Gaitmaster (JR)
P Knees Mauch® Knee
P Knees Mauch® Plus Knee
P Knees Safety Knee
P Knees SNJ cylinder
P Knees SNS cylinder
P Knees Total Knee® – Model #1100
P Knees Total Knee® – Model #1900
P Knees Total Knee® – Model #2000
P Knees Total Knee® – Model #2100
P Knees Cheetah® Knee
P Liners Iceform®
P Liners Iceform® Sleeve
P Liners Iceross Activa®
P Liners Iceross Comfort®
P Liners Iceross Comfort Cushion®
P Liners Iceross Comfort® Wave Silken
P Liners Iceross Dermo®
P Liners Iceross Dermo® Junior
P Liners Iceross Dermo® Seal-In®
P Liners Iceross Dermo® Cushion
P Liners Iceross Dermo® Conical Wave
P Liners Iceross Dermo® Wave
P Liners Iceross® Distal Cup
P Liners Iceross® Original



P Liners Aspire™ Liner

P Liners Iceross® Liner Socks

P Liners Iceross® Pads

P Liners Iceross® Post-Op

P Liners Iceross Seal-In®

P Liners Iceross Seal-In® V

P Liners Iceross Seal-In® Wave

P Liners Iceross Seal-In® X

P Liners Iceross Seal-In® X TF

P Liners Iceross® Sleeve

P Liners Iceross® Sport

P Liners Iceross Stabilo® Junior

P Liners Iceross® Synergy

P Liners Iceross® Synergy Cushion

P Liners Iceross® TF Seal-In

P Liners Iceross® Seal-In X5

P Liners Iceross® Transfemoral

P Liners Iceross® Upper-x

P Locks and Sleeves Iceflex® Balance

P Locks and Sleeves Iceflex® Endurance

P Locks and Sleeves Iceross® Sleeve

P Locks and Sleeves Icelock® 100 series

P Locks and Sleeves Icelock® 200 series

P Locks and Sleeves Icelock® 300 series

P Locks and Sleeves Icelock® 400 series

P Locks and Sleeves Icelock® 500 series

P Locks and Sleeves Icelock® 600 series

P Locks and Sleeves Icelock® 700 series

P Other Patient Activity Monitor (PAM)

P Other Össur® Rigid Dressing

P Sockets Össur Brim

P Sockets Pressure Pads



P Sockets Modular Socket System

B&S Spinal Lil' Angel® Halo
B&S Spinal ReSolve® Halo
B&S Spinal J-Tongs™
B&S Spinal Halo accessories

P Feet PROPRIO FOOT™ Plus
P Feet PROPRIO FOOT™ Plus with Unity
P Feet SYMBIONIC™ Leg 3
P Knee RHEOLOGIC™
P Knee RHEO KNEE® 3
P Knee RHEO KNEE® II
P Knee RHEO KNEE® XC
P Knee POWER KNEE™

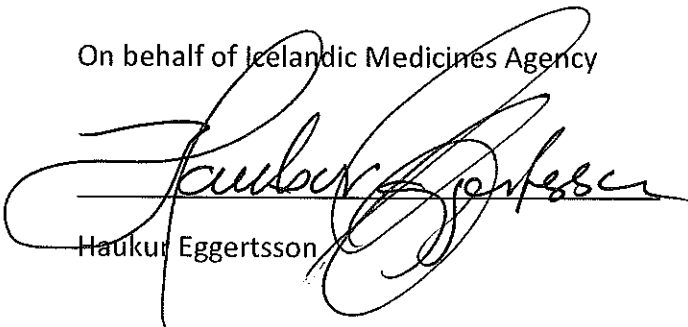
Abbreviations:

P: Prosthetics
B&S: Braces and supports

Icelandic Medicines Agency certifies that Össur hf., Grjóthálsi 2, 110 Reykjavík, Iceland is a registered manufacturer according to Icelandic law and regulation and Dir. 93/42/EEC and is authorised to develop, manufacture and sell on the Icelandic market and to export without any restrictions the medical devices above mentioned.

This certificate is valid until April 3rd, 2022.

On behalf of Icelandic Medicines Agency


Haukur Eggertsson

