By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 78541**

Issued To: **Össur hf.**
Grjothals 1-5
Reykjavik
110
Iceland

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

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-05-17** Date: **2020-12-21** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 78541

Issued To:

Össur hf.
Grjothals 1-5
Reykjavik
110
Iceland

Number	Device Name	Intended purpose per IFU
Class IIb		
60367	Halo System	Intended for use to provide traction along the cervical spine to align the vertebral structures (reduce deformities), maintain reduction, or provide stabilization.
46528	J-Tongs	Intended for use to provide longitudinal traction along the cervical spine to align the vertebral structures (reduce deformity), maintain reduction, or provide stabilization.
Class IIa		
MD 1108	Powered Knee	N/A
MD 1108	Powered Ankle	N/A

First Issued: **2004-05-17** Date: **2020-12-21** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 78541**
Date:	**2020-12-21**
Issued To:	**Össur hf.** **Grjothals 1-5** **Reykjavik** **110** **Iceland**

Subcontractor:	**Service(s) supplied**
Ossur Americas 27051 Towne Centre Drive, Suite 100 Foothill Ranch California 92610 USA	**Design**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 78541**
Date: **2020-12-21**
Issued To: **Össur hf.**
Grjothals 1-5
Reykjavik
110
Iceland

Date	Reference Number	Action
17 May 2004		Certificate issue
24 August 2005		Change to scope to include powered prosthetic knees, the addition of sterile to silicone wound dressings and addition of Victhom Bionique Humaine (Québec) as a sub contractor.
October 2005		Addition of Steripack Limited as a subcontractor for packaging.
25 September 2008		Addition of Sterigenics Germany as a subcontractor for ETO sterilization.
19 June 2009	7378076	Certificate re-issue. Removal of 'sterile wound dressings' from scope. Addition of 'cranial traction systems'. Removal of the following as sub-contractors: 'Isotron Ireland Ltd', 'Steripack Limited', Sterigencis Germany GmbH'. Addition of the following as sub-contractors: 'Ossur Americas, Inc.', 'HPC MEDX', Centurion Sterilization Services' and 'NASP'.
14 January 2011	7625139	The addition of "and sterile and non-sterile" to the scope, also the removal of Victhom Bionique Humaine as a significant subcontractor.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 78541**
Date: **2020-12-21**
Issued To: **Össur hf.**
Grjothals 1-5
Reykjavik
110
Iceland

Date	Reference Number	Action
22 June 2011	7665577	Change to scope from "The design and manufacture of powered prosthetic knees and sterile and non-sterile cranial traction systems" to "The design and manufacture of microprocessor controlled, powered and non-powered, knee and ankle systems; and sterile and non-sterile cranial traction" systems.
05 September 2012	7900615	Change of site for the sterilisation subcontractor, also a change in part of the subcontractor name. From, 'Centurion Sterilization Services Division of Tri-States Hosp. Supply, 301 Catrell Drive, Howell, Michigan 48843, USA'. To, 'Centurion Sterilization Services a Division of Centurion Medical Products Corporation, 3310 South Main St., Salisbury, North Carolina 28147, USA.
02 June 2014	8149756	Certificate Renewal.
14 February 2019	8888015	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 78541**
Date: **2020-12-21**
Issued To: **Össur hf.**
Grjothals 1-5
Reykjavik
110
Iceland

Date	Reference Number	Action
14 June 2019	9719484	Certificate renewal. Addition of device supplementary table. Change of name of subcontractor from 'NASP' to 'Cosmed Group, Inc. d/b/a Cosmed of NJ'. Addition of subcontractor 'Ossur Americas, 27051 Towne Centre Drive, Suite 100, Foothill Ranch, California 92610, USA' for provision of design and manufacture. Correction of part of the subcontractor name from 'Ossur Americas, Inc.' to 'Ossur Americas'. Amendment of part of subcontractor name from 'Centurion Sterilization Services' to 'Centurian Medical Products Corporation'.
Current	3339624	Removal of the following subcontractors, due to discontinuation of manufacturing of sterile and non-sterile traction devices: Centurion Sterilization Services, HPC MEDX, Cosmed Group, Inc. d/b/a Cosmed of NJ; Removal of the following subcontractor (client manufacturing site) due to closure: Ossur Americas, Inc. Amendment of subcontractor activities at Ossur Americas, 27051 Towne Centre Drive, Suite 100, Foothill Ranch, California to remove manufacturing.