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 0086):

Gary Fenton, Global Assurance Director

First Issued: **17 May 2004** Date: **02 June 2014** Expiry Date: **18 June 2019**

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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: **02 June 2014**

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Iceland

Subcontractor:	Service(s) supplied
Centurion Sterilization Services A Division of Centurion Medical Products Corporation 3310 South Main St. Salisbury North Carolina 28147 USA	**ETO Sterilization** **Packaging**
HPC MEDX 14 Industrial Drive Hanover Pennsylvania 17331 USA	**Packaging**
NASP 19 Park Drive Franklin New Jersey 07416 USA	**ETO Sterilization**

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List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
Ossur Americas, Inc. 910 Burstein Drive Albion Michigan 49224 USA	**Assembly** **Final Inspection**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 78541**
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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

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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