By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 552745**

Issued To: **Medos International SARL**
Chemin-Blanc 38
Le Locle
CH-2400
Switzerland

In respect of:

See certificate scope page.

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: **2009-11-11** Date: **2021-05-20** Expiry Date: **2024-05-26**

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Certificate No: CE 552745

Certificate Scope:

Sports Medicine
Absorbable and non-absorbable orthopaedic implant devices, class IIa instrumentation, accessories and powered accessories, fluid management systems and accessories, RF surgical equipment and sterile electrodes.

Neurology
Neurovascular devices (infusion/microcatheters and intermediate catheters, balloon catheters, steerable guidewires, guiding catheters, thrombectomy devices, vascular occlusion devices and intracranial vascular stents)

Spinal
Sterile and non-sterile implant and instrumentation systems, synthetic bone graft material, spinal cement and cement delivery systems, accessory needles, devices for stimulation and nerve mapping and additively manufactured sterile cervical intervertebral body fusion devices.

First Issued: **2009-11-11** Date: **2021-05-20** Expiry Date: **2024-05-26**

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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 552745**
Date:	**2021-05-20**
Issued To:	**Medos International SARL** **Chemin-Blanc 38** **Le Locle** **CH-2400** **Switzerland**

Subcontractor:	**Service(s) supplied**
Atrion Medical Products Inc. 1426 Curt Francis Road Arab Alabama 35016 USA	**Manufacture**
Chemence Medical, Inc. 200 Technology Drive Alpharetta Georgia 30005 USA	**Manufacture**
Codman & Shurtleff Inc. 325 Paramount Drive Raynham Massachusetts 02767-0350 USA	**Control of Sterilization** **Design** **Development** **Manufacture**

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

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Issued To:	**Medos International SARL** **Chemin-Blanc 38** **Le Locle** **CH-2400** **Switzerland**

Subcontractor:	**Service(s) supplied**
Codman & Shurtleff, Inc. dba DePuy Synthes Products, Inc. 47709 Fremont Blvd Fremont California 94538 USA	**Final Inspection** **Manufacture**
Codman & Shurtleff, Inc. 6303 Blue Lagoon Drive, Suite 315 Miami FL 33126 USA	**Design**
Codman & Shurtleff, Inc. dba DePuy Synthes Products, Inc 3260 Executive Way Miramar FL 33025-3930 USA	**Final Inspection** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Codman and Shurtleff, Inc Calle Circuito Interior Norte #1820 Parque Industrial Salvarcar Ciudad Juarez Chihuahua C.P. 32574 Mexico	**Final Inspection** **Manufacture** **Packaging**
Concert Medical, LLC 77 Accord Park Drive Norwell MA 02061 USA	**Manufacture**
Confluent Medical Technologies, Inc 47533 Westinghouse Drive Fremont CA 94539 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Cordis Corporation 14201 North West 60th Avenue Miami Lakes Florida 33014 USA	**Manufacture**
DePuy International Limited Trading as DePuy CMW Cornford Road Blackpool Lancashire FY4 4QQ United Kingdom	**Control of Sterilization** **Design** **Manufacture**
DePuy Ireland UC Loughbeg Ringaskiddy Co. Cork Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System

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List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
DePuy Mitek, Inc 325 Paramount Drive Raynham Massachusetts 02767 USA	**Control of Sterilization** **Design** **Development** **Manufacture**
DePuy Orthopedics, Inc. 50 Scotland Boulevard Bridgewater Massachusetts 02324 USA	**Final Inspection**
DePuy Spine, Inc. 325 Paramount Drive Raynham Massachusetts 02767 USA	**Control of Sterilization** **Design** **Development** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations Inc 435 Whitney Street Northborough Massachusetts 01532 USA	**ETO Sterilization**
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	**Radiation (Gamma Sterilization)**
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Smart World LLC, dba Steri-Tek 48225 Lakeview Blvd., Fremont California 94538 USA	**Radiation (E Beam Sterilization)**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Sterilization Services of Georgia, Inc. 6005 Boat Rock Boulevard Atlanta Georgia 30336 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma California 94954 USA	**Radiation (E Beam Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 552745**
Date: **2021-05-20**
Issued To: **Medos International SARL**
Chemin-Blanc 38
Le Locle
CH-2400
Switzerland

Date	Reference Number	Action
11 November 2009	7432195	First issue.
16 November 2010	7602511	Scope modification, addition of 'Biocide-based disinfectants for use with invasive medical devices' and addition of 'Advanced Sterilisation Products, A Johnson & Johnson Company, Division of Ethicon, Inc. CA 92618-9824' to significant list of sub contractors for deign, development & manufacturing sub contractor activities.
30 January 2012	7778831	The inclusion of Micrus products requires a scope clarification to include 'intravascular catheter'.
22 August 2012	7869233	Scope modification – addition of "balloon catheters", "thrombectomy devices", "intracranial vascular stents" and "infusion/microcatheters and intermediate catheters".
08 November 2012	7914134	Addition of 'DePuy International Ltd T/A DePuy CMW, Cornford Road, Blackpool, Lancashire, UNITED KINGDOM FY4 4Q' to significant list of subcontractors for design & manufacture subcontractor activities. Addition of 'Medos SARL, Chemin Blanc, 36, Le Locle, CH-2400, Switzerland' to significant list of subcontractors for manufacture subcontractor activity. Addition of 'DePuy Motion SARL, Chemin Blanc 38, Le Locle, CH-2400, Switzerland' to significant list of subcontractors for manufacture subcontractor activity.

EC Certificate - Full Quality Assurance System Certificate History

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Switzerland

Date	Reference Number	Action
20 March 2013	7957159	Addition of 'Medos SARL, Chemin Blanc, 38, Le Locle, CH-2400 Switzerland' to significant list of subcontractors for manufacture subcontractor activity. Addition of 'Medos Sarl, Puits Godet 20, Neuchâtel, CH – 2000, Switzerland' to significant list of subcontractors for manufacture subcontractor activity. Addition of 'Medos SARL, Rue Girardet 29, Le Locle, CH-2400 Switzerland' to significant list of subcontractors for manufacture subcontractor activity. Minor formatting changes to subcontractor addresses.
26 September 2013	8032096	Removal of Subcontractors: "DePuy Motion SARL, Chemin Blanc 38, Le Locle, CH – 2400 Switzerland" "Medos Sarl, Chemin Blanc 36, Le Locle, CH – 2400 Switzerland" "Medos Sarl, Chemin Blanc 38, Le Locle, CH – 2400 Switzerland" "Medos Sarl, Puis Godet 20, Nechater, CH – 2400 Switzerland" "Medos Sarl, Rue Girardet, Le Locle, CH – 2400 Switzerland" "DePuy Orthopedics Inc, 700 Orthopedic Drive, Warsaw, In 46582, USA".
7 January 2014	8094307	Changes only to the Sports Medicine section of the scopes to include sterile single-use instruments, accessories, fluid management systems and accessories.

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Date	Reference Number	Action
30 October 2014	8244291	Certificate Renewal. Removal of "Trauma" section from Scope Removal of "DePuy France SAS" as subcontractor Addtion of "Control of Sterilization" as service for "Depuy International Limited, T/A DePuy CMW".
24 June 2016	8416579	Added ethylene oxide sterilization chamber, chamber #4, and modified sterilization protocol in chamber #3 to align with the protocol in chamber #4, for Codman & Shurtleff's contract sterilizer Sterigenics Belgium (Petit Rechain).
15 August 2017	8786669	Added Codman (Fremont) as a subcontractor for the services of manufacture, final inspection, and distribution.
11 September 2017	8792054	Scope extension to include acrylic resins for neurosurgery.
8 June 2018	8901983	Removal of "Cartilage autograft implantation system (CAIS)" from scope" Removal of "Distribution" as service for "Codman & Shurtleff, Inc, dba DePuy Synthes Products, Inc".
03 August 2018	8904338	Added the following subcontractors: Codman & Shurtleff, Inc., 6303 Blue Lagoon Drive, Suite 315, Miami, FL 33126 for the Service of Design; Lake Region Medical, 340 Lake Hazeltine Drive, Chaska, MN 55318 for the Service of Manufacture; DePuy Inc., 50 Scotland Boulevard, Bridgewater, MA-02324, for the services of Final Inspection; Isomedix Operations, Inc., 435 Whitney Street, Northborough, MA 01532 for the service of ETO sterilization.

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Date	Reference Number	Action
04 March 2019	7779215	Traceable to NB 0086.
08 November 2019	3068222	Certificate Renewal. Addition of the following subcontractors Atrion Medical Products, Inc (Manufacture); Concert Medical, LLC (Manufacture); Cordis Corporation (Manufacture); Codman & Shurtleff, Inc. dba DePuy Synthes Products, Inc, Miramar (Manufacture & Final Inspection); Codman & Shurtleff, Chihuahua (Manufacture, Inspection, Packaging); Confluent Medical Technologies, Inc (Manufacture); Sterilization Services of Georgia, Inc (ETO Sterilisation); Isomedix Operations, Inc, Whippany (Gamma Sterilisation); Synergy Health AST, LLC (E-beam Sterilisation) Removal of subcontractors Advanced Sterilisation Products Change name of "DePuy, Inc" to "DePuy Orthopedics, Inc." Removal of "Disinfectants – Biocide-based disinfectants for use with invasive medical devices" from the scope.
24 April 2020	3152674	Extension of scope to include "devices for stimulation and nerve mapping".
27 August 2020	3222038	Extension of scope to include "additively manufactured sterile cervical intervertebral body fusion devices."
01 October 2020	3279874	Added Sterigenics, Harold Gatty Drive, as an ETO sterilization subcontractor.
07 April 2021	3367539	Add subcontractor Chemence Medical, Inc. for Manufacture.

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Date	Reference Number	Action
20 May 2021	3346530	Restricted – removal of general non-powered surgical instruments, neurosurgical devices (aneurysm clips, high speed drill systems, surgical patties, acrylic resins for neurosurgery, surgical single use sterile devices and sterile kits, cranial endoscopes/ electrodes, catheters and vascular access ports and accessories), fluid drainage/monitor systems and accessories, spinal and absorbable fixation devices, electrosurgical products and generators, dural substitutes.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
06 August 2021	3410308	Addition of Smart World LLC, dba Steri-Tek, Fremont, CA, USA, as a qualified E Beam sterilization facility. Addition of DePuy Ireland UC, Loughbeg, Ringaskiddy, Co. Cork, Ireland, as EU Representative.

Inspiring trust for a more resilient world.

06 August 2021

Medos International SARL
Chemin-Blanc 38
Le Locle
CH-2400
Switzerland

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 552745	93/42/EEC Annex II excluding Section 4	3410308	Addition of Smart World LLC, dba Steri-Tek, Fremont, CA, USA, as a qualified E Beam sterilization facility. Addition of DePuy Ireland UC, Loughbeg, Ringaskiddy, Co. Cork, Ireland, as EU Representative.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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