By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 724423 R000

Manufacturer: Medos International SARL

Address:
Chemin Blanc 38
Le Locle
CH-2400
Switzerland

Single Registration Number: CH-MF-000014268

EU Authorised Representative: DePuy Ireland UC

Address:
Loughbeg
Ringaskiddy
Co. Cork
Ireland

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.14 17:09:22 EEST
Reason: MoldSign Signature
Location: Moldova

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-12-23** Date: **2022-04-21** Expiry Date: **2025-12-22**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class III and Class IIb devices

Class III	**Intended purpose**
Microcatheters	See MDR 756263
ENVOY Distal Access Guiding Catheter	See MDR 743860
Class IIb, Implantable, Well-established technologies	**Intended purpose**
Non-absorbable Suture Anchors	Intended for soft tissue to bone reattachment.
Lumbar Spinal Fusion Cages	Intended for lumbosacral intervertebral body fusion.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Microcoil Detachment Control Box	Class IIa
Reusable Instruments 'Orthopaedic Instruments'	Class Ir
Reusable Instruments 'Orthopaedic Instruments'	Class Ir, Class Im
Orthopaedic Instruments	Class Im
Sterile Instruments 'Orthopaedic Instruments'	Class Is
Electrosurgical Devices	Class Is
Arterio-Venous Devices	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2020-12-23	3147583	Issued.
2021-10-28	3542752	Supplemented – Addition of device categories: Microcoil Detachment Control Box, Non-absorbable Suture Anchors and Lumbar Spinal Fusion Cages. Compliance to e-IFU Regulation 207/2012. Addition of subcontractors Ethicon Inc., Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda., Medistri SA and Medos Sarl. Addition of 'Manufacture' and 'Control of Sterilization' for existing subcontractor Jabil Switzerland Manufacturing GmbH. Amended – Addition of Single Registration Number. Administrative update to Device Schedule to add 'Class' in Risk Classification column, change 'Ir & m' to 'Class Ir, Class Im' and change 'Sterile instruments' to 'Sterile Instruments'
2022-03-17	3639909	Amended – addition of subcontractor: Codman and Shurtleff, Inc. (Ciudad Juarez, Mexico) Supplemented – Addition of Class III microcatheters Amended – Administrative update to prior history entries to follow YYYY-MM-DD format.
Current	3678270	Supplemented – Addition of Class III ENVOY Distal Access Guiding Catheters. Amended – Addition of subcontractors Codman & Shurtleff, Inc. (Miramar, Florida) and Sterilization Services of Georgia.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

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Date: **2022-04-21**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Atrion Medical Products Inc. 1426 Curt Francis Road Arab Alabama 35016 USA	**Manufacture**
Codman & Shurtleff, Inc. dba DePuy Synthes Products, Inc. 3260 Executive Way Miramar Florida 33025 USA	**Manufacture**
Codman & Shurtleff, Inc. dba DePuy Synthes Products, Inc. 47709 Fremont Blvd Fremont California 94538 USA	**Final Inspection** **Manufacture** **Packaging**
Codman & Shurtleff, Inc. 6303 Blue Lagoon Drive, Suite 315 Miami FL 33126 USA	**Design**

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Codman and Shurtleff, Inc. Calle Circuito Interior Norte #1820 Parque Industrial Salvarcar Ciudad Juarez Chihuahua C.P. 32574 Mexico	**Final Inspection** **Manufacture** **Packaging**
DePuy Mitek A Johnson & Johnson Company 325 Paramount Drive Raynham Massachusetts 02767 USA	**Design**
DePuy Orthopaedics, Inc. 50 Scotland Blvd Bridgewater Massachusetts 02324 USA	**Final Inspection**
DePuy Spine 325 Paramount Drive Raynham Massachusetts 02767 USA	**Design**

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Critical Subcontractor/Crucial Supplier	Service(s) supplied
Ethicon, Inc. 655 Ethicon Circle Cornelia Georgia 30531 USA	**Manufacture**
Harmac Medical Products, Inc. 2201 Bailey Avenue Buffalo, NY 14211-1797 USA	**Packaging**
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	**Ethylene oxide gas sterilization (ETO, EOG)**
Jabil Switzerland Manufacturing GmbH Chemin Blanc 36-38 Le Locle 2400 Switzerland	**Control of Sterilization** **Manufacture** **Packaging**
Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. Rod. Presidente Dutra - KM 154 São José dos Campos São Paulo 12240-908 Brasil	**Manufacture**

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Medistri SA Rte de L'Industrie 96 1564 Domdidier Switzerland	**Ethylene oxide gas sterilization (ETO, EOG)**
Medos Sarl Rue du Puits-Godet 20 Neuchâtel CH-2000 Switzerland	**Manufacture** **Packaging**
Paragon Medical Inc. 125 W 1000 South Smithfield Utah 84335 USA	**Manufacture**
Sterilization Services of Georgia 6005 Boatrock Blvd. Atlanta Georgia 30336 USA	**Ethylene oxide gas sterilization (ETO, EOG)**
Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma California 94954 USA	**Radiation (E Beam Sterilization)**

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Date: **2022-04-21**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Synergy Health Däniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	**Radiation (Gamma Sterilization)**
T.A.G. Medical Products Corporation Ltd. Kibbutz Gaaton 2513000 ISRAEL	**Manufacture**

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