Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 4 din 13.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albişoara 16/1 of.7, or. Chişinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Intravascular Guiding Catheter

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.10.13 17:09:28 EEST
Reason: MoldSign Signature
Location: Moldova

Data 13.10.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 17:11:19 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Intravascular Guiding Catheter

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 13.10.2023

LifeTech Consulting s.r.l.
Str. Vulturilor nr. 56-58, Sector 3, București
RO26420806 - J40/603/2010
ING Bank Sucursala Bucuresti
RO24INGB0000999901828832
tel/fax: 021 323 3016 - mobil: 0721 285085
email: office@life-tech.ro

To: Whomever it may concern

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

26.10.2022

MANUFACTURERS AUTHORIZATION

We, **Lifetech Consulting S.R.L.**, authorized distributor of **Medos International SARL a Johnson & Johnson company**, manufacturer of medical products with principal place of business at Chemin Blanc 38, Le Locle CH-2400, Elveția, hereby confirm that **Biosistem mld SRL** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized by the company **Lifetech Consulting S.R.L.**, to carry out the registration of products manufactured by **Medos International SARL a Johnson & Johnson company** in Republic of Moldova.

This authorization is valid for 1 year from the date of issuance and automatically renewable if no termination letter issued.

Bogdănel Scripcă

Legal representative

Lifetech Consulting S.R.L.

Declaration of Conformity
CEREBASE DA Guide Sheath
Design Dossier DD-056-DOC, Revision 1

Manufacturer:
Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Notified Body:
BSI
Identification Number: 2797

Full Quality Assurance Certificate CE 552745
Design Examination Certificate CE 720268

Products:
See Attached

Classification:
Class III, Rule 6 of Annex IX of the MDD 93/42/EEC

Start of CE Marking:
See Attached

Conformity Assessment Route:
MDD Annex II Section 3.2, including Section 4

We declare that the above-mentioned products meet the provisions of the legislation transposing European **Medical Devices Directive 93/42/EEC** concerning Medical Devices into the laws of the European Economic area.
All supporting documentation is available under the premises of the manufacturer.

_____ 15/04/2020

Vivian Perez
Associate Director Regulatory Affairs
Medos International SARL

DD/MM/YYYY

_____ _____

Nicolas Hainard
Senior Quality Operations Manager
Medos International SARL

DD/MM/YYYY

CEREBASE DA Guide Sheath - DD-056-DOC, Revision 1						
Product Code	**Description**	**Sterile/Non-Sterile**	**CE Mark Date**	**Classification**	**GMDN Code**	**GMDN Code Description**
GS9095SD	CEREBASE DA Guide Sheath, 95cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter
GS9090SD	CEREBASE DA Guide Sheath, 90cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter
GS9080SD	CEREBASE DA Guide Sheath, 80cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter
GS9070SD	CEREBASE DA Guide Sheath, 70cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter

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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By Royal Charter

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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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**
Codman & Shurtleff, Inc. dba DePuy Synthes Products, Inc 3260 Executive Way Miramar FL 33025-3930 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. 47709 Fremont Blvd Fremont California 94538 USA	**Final Inspection** **Manufacture**

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**
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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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**
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

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**
DePuy Mitek A Johnson & Johnson Company 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 325 Paramount Drive Raynham Massachusetts 02767 USA	**Control of Sterilization** **Design** **Development** **Manufacture**

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**
Isomedix Operations Inc 435 Whitney Street Northborough Massachusetts 01532 USA	**ETO Sterilization**
Isomedix Operations, Inc 1175 Isuzu Parkway Grand Prairie Texas 75050 USA	**ETO Sterilization**
Isomedix Operations, Inc 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**

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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**
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**
Smart World LLC, dba Steri-Tek 48225 Lakeview Blvd., Fremont California 94538 USA	**Radiation (E Beam Sterilization)**

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**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**
Sterilization Services of Georgia, Inc. 6005 Boat Rock Boulevard Atlanta Georgia 30336 USA	**ETO Sterilization**

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**
Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma California 94954 USA	**Radiation (E Beam Sterilization)**
Synthes GmbH Industriestrasse 28 CH-2545 Selzach Switzerland	**Final Inspection**

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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

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
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.

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
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.

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
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.

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
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.
19 April 2022	3564812	Addition of additional subcontractors: Synthes GmbH, Isomedix Operations, Inc (Texas and California), Sterigenics US, LLC. Removal of "Inc." for Depuy Mitek and Depuy Spine.

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19 April 2022

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	3564812	Addition of additional subcontractors: Synthes GmbH, Isomedix Operations, Inc (Texas and California), Sterigenics US, LLC. Removal of "Inc." for Depuy Mitek and Depuy Spine.

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,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

EC Design-Examination Certificate

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

No. **CE 720268**

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

In respect of:

CEREBASE DA Guide Sheath

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-04-13** Date: **2020-04-13** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 720268

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GS9095SD	CEREBASE DA Guide Sheath	95cm	The CEREBASE DA Guide Sheath is indicated for the introduction of interventional devices into the neuro vasculature	Class III
GS9090SD		90cm		
GS9080SD		80cm		
GS9070SD		70cm		

First Issued: **2020-04-13** Date: **2020-04-13** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 720268

Issued To:

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

Certificate History

Date	Reference Number	Action
Current	3097316	First Issue.

First Issued: **2020-04-13** Date: **2020-04-13** Expiry Date: **2024-05-26**

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Supplementary Information to CE 720268 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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

Date: 28 February 2022

Changes Approved:

Date	Reference Number	Action
28 February 2022	3563245	Change in shelf life from 18 months to 26 months for the CEREBASE DA Guide Sheath.

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28 February 2022

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 720268	93/42/EEC Annex II Section 4	3563245	Change in shelf life from 18 months to 26 months for the CEREBASE DA Guide Sheath.

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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl