ORDIN DE PLATA NR.: 11 TIP.DOC. 1

DATA EMITERII:2 februarie 2023

PLATITI: 1500-00 LEI: Una Mie Cinci Sute lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD44ML000000002251729503
CODUL FISCAL :1007600044280 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. suc."Invest" Chisinau
CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R)IMSP Institutul de medicina urgenta
CONTUL DE PLATI/CODUL IBAN
MD55VI022510300000002MDL
CODUL FISCAL :1003600152606 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.
CODUL BANCII:
:VICBMD2X :

DESTINATIA PLATII:Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1674466049029 din 03.02.2023

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:02/02/2023
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii
MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV

(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii
MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV

L.S. (semnatura electronica)

CONDUCATOR: _____ (semnatura manuala)

CONTABIL-SEF: _____ (semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2023.02.02 17:52:00 EET
Reason: MoldSign Signature
Location: Moldova

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8871** din **05.05.2021**

Denumirea completă: **Societatea Comercială «OXIVIT-MED» S.R.L.**
Denumirea prescurtată: **S.C. «OXIVIT-MED» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
2 Comerţul cu ridicata al parfumurilor şi produselor cosmetice;
3 Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerţ cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerţ cu ridicata;
7 Închirierea altor maşini şi echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociaţi:
1. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 5400.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 05.05.2021.

Specialist coordonator
tel. 022-207-840
Lazari Aliona

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 635352**

Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

In respect of:

Design, Development, and Manufacture of Sterile Neurovascular Stents and Stent Delivery Systems, Neuro and Peripheral Vascular Embolization Coils, Coil Detachment Systems, Guidewires, Distal Access Catheters, Delivery Assist Catheters, Occlusion Balloon Catheters and Neuro, Peripheral and Coronary Vascular Microcatheters, Flow Diverters.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of Rotating Hemostatic Valves.

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: **2015-06-01** Date: **2020-04-29** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 635352

Issued To:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Number	Device Name	Intended purpose per IFU
Class III		
---	AXS Catalyst™ Distal Access Catheter	See CE 632309
---	AXS Offset™ Delivery Assist Catheter	See CE 632309
---	AXS Infinity LS Long Sheath	See CE 694301
---	Excelsior® 1018® Pre-shaped Microcatheters	See CE 635354
---	Excelsior® 1018® Reinforced Microcatheters	See CE 635354
---	Excelsior® SL-10® Pre-shaped Microcatheters	See CE 635354
---	Excelsior® SL-10® (Straight) Microcatheters	See CE 635354
---	Excelsior® XT-17™ Microcatheters	See CE 635354
---	Excelsior® XT-27® (Straight and Pre-shaped)	See CE 635354
---	Neuroform Atlas™ Stent System	See CE 632308
---	Neuroform EZ™ 3 Stent System	See CE 644526
---	Surpass Streamline™ Flow Diverter	See CE 644527
---	Surpass Evolve™ Flow Diverter System	See CE 700283
---	Synchro® Guidewires (-10 and -14)	See CE 637956
---	Synchro²® Guidewires	See CE 637954
---	Target™ Detachable Coils	See CE 635353
---	TransForm™ Occlusion Balloon Catheters	See CE 645956
---	Trenza™ Embolization Device	See CE 709778
---	Wingspan™ Stent System	See CE 644523

First Issued: **2015-06-01** Date: **2020-04-29** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 635352

Issued To:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Class IIa		
NBOG code: MD 1104	InZone Detachment System	---
Class Is		
NBOG code: MD 0102	Rotating Hemostatic Valve (RHV), Box of 5	---

First Issued: **2015-06-01** Date: **2020-04-29** Expiry Date: **2024-05-26**

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By Royal Charter

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 635352**
Date:	**2020-04-29**
Issued To:	**Stryker Neurovascular** **47900 Bayside Parkway** **Fremont** **California** **94538** **USA**

Subcontractor:	**Service(s) supplied**
Benchmark Electronics, Inc. Minnesota Division, Winona location 4065 Theurer Blvd. Winona Minnesota 55987 USA	**Manufacture**
Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica	**Manufacture**
Boston Scientific Corporation Two Scimed Place Maple Grove Minnesota 55311 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 635352**
Date:	**2020-04-29**
Issued To:	**Stryker Neurovascular** **47900 Bayside Parkway** **Fremont** **California** **94538** **USA**

Subcontractor:	**Service(s) supplied**
Boston Scientific Limited Business and Technology Park Model Farm Road Cork Ireland	**Manufacture**
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**
Isomedix Operations, Inc. 9120 South 150 East Sandy Utah 84070 USA	**Radiation (Gamma Sterilization)**

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By Royal Charter

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 635352**
Date:	**2020-04-29**
Issued To:	**Stryker Neurovascular** **47900 Bayside Parkway** **Fremont** **California** **94538** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Stryker European Operations B.V Herikerbergweg 110 Amsterdam 1101 CM The Netherlands	**EU Representative**
Stryker Neurovascular 4870 West 2100 South Salt Lake City Utah 84120 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 635352**
Date:	**2020-04-29**
Issued To:	**Stryker Neurovascular** **47900 Bayside Parkway** **Fremont** **California** **94538** **USA**

Subcontractor:	**Service(s) supplied**
Stryker Neurovascular Business & Technology Park Model Farm Road Cork Ireland	**Manufacture**
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 635352**

Date: **2020-04-29**

Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

Date	Reference Number	Action
01 June 2015	8332563	Transfer from another Notified Body.
21 August 2015	8365050	Addition of Excelsior XT-17 Microcatheters to scope.
18 December 2015	8364858	Transfer from another Notified Body of the following devices: Synchro® 10 & 14 and Synchro2® Guidewires, Guglielmi Detachable Coils, Matrix^{2}® Detachable Coils, Wingspan® Stent System, Excelsior® family of Microcatheters (SL-10® Pre-Shaped, 1018® Reinforced, 1018® Pre-shaped, XT-27®), Tracker®-17 Microcatheters, FasTracker®10 & 18 and 18 MX Microcatheters and TransForm® Occlusion Balloon Catheters. Addition of signification subcontractors, Lake Region Medical, Pulse Systems, Sterigenics, and three STERIS Isomedix locations (Spartanburg, SC, Sandy, UT and Libertyville, IL).
10 February 2016	8457194	Consolidation of the scope of CE 632307 with CE 635352 and obsolescence of CE 632307. Correction of First Issued Date from December 18, 2015 to June 1, 2015. Addition of "Flow Diverters" from the scope CE 632307. Products include; Atlas Stent System, AXS catalyst Distal Access Catheter, Neuroform EZ and 3 Microdelivery Stent Systems, and Surpass Stream Line Flow Diverter. Addition of subcontractors and crucial suppliers from CE 632307, Secant Medical, NDC (Nitinol Devices & Components), and Heraeus Medical Components LLC. Addition of Sterigenics, Willowbrook, IL that was inadvertently omitted during the transfer.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 635352**

Date: **2020-04-29**

Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

Date	Reference Number	Action
09 August 2016	8571667	Change of EU Representative from RAQA Manager Stryker France S.A.S. to Stryker European Operations B.V. Remove EU Representative information from all locations except the outer packaging product carton.
11 January 2017	8661493	Addition of Delivery Assist Catheters to the scope.
07 April 2017	8653826	Update of name of subcontractor NDC to Confluent Medical Technologies, Inc. Update the name Secant Medical, Inc. to The Secant Group, LLC, and update the address. Add the Trenton, Georgia, and Malaysia locations for Lake Region Medical to the certificate as significate subcontractors for manufacturing.
12 May 2017	8714504	Certificate renewal.
03 November 2017	8792659	Add Venusa de Mexico S. A. de C.V. to the certificate as a subcontractor for manufacturing. Add AdvanSource Biomaterials (ASB) to the certificate as a supplier of material crucial for the transform occlusion balloon catheter. Remove Steris Isomedix Services in Spartanburg, SC from the certificate, as this subcontractor is no longer used.
26 February 2018	8876758	Addition of Stryker (Salt Lake City, UT) for the activity of "Manufacture."

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 635352**

Date: **2020-04-29**

Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

Date	Reference Number	Action
20 March 2018	8855764	The name for the Salt Lake City site was corrected to Stryker Neurovascular.
25 January 2019	8366187	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 635352**
Date: **2020-04-29**
Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

Date	Reference Number	Action
06 March 2020	9769092	Addition of product supplementary information table. Removal of "Connecting Cables" from the scope of the certificate. Addition of subcontractors/suppliers: Boston Scientific Limited - Cork, Ireland; Boston Scientific Corporation – Heredia, Costa Rica; Boston Scientific Corporation - Maple Grove, Minnesota, USA. Addition of "Minnesota Division, Winona location" to address of "Benchmark Electronics, Inc.". Correction of "Synerg Health Ireland Ltd" to "Synergy Health Ireland Ltd" and removal of "Sragh". Rectification of subcontractor/supplier designation in line with ISO 13485 certificate: "STERIS Isomedix Services Inc." to "Isomedix Operations, Inc. North Facility" for the site in Libertyville, Illinois, 60048, USA, (MD 89745); "STERIS Isomedix Services Inc." to "Isomedix Operations, Inc." for the site in Sandy, Utah, 84070, USA (MD 89745). Removal of Stryker Neurovascular – West Valley City, USA. Removal of subcontractors/suppliers: AdvanSource Biomaterials (ASB) - USA; Confluent Medical Technologies Inc. - USA; Heraeus Medical Components LLC - USA; Lake Region Medical – Butlerland, Ireland; Lake Region Medical – Penang, Malaysia; Lake Region Medical - Trenton, Georgia, USA; Lake Regional Medical - Venusa de Mexico S.A. de C.V. - Juarez, Mexico; Pulse Systems - USA; Sterigenics - Willowbrook, Illinois, USA; The Secant Group, LLC - USA.
Current	9758755	Certificate renewal.

stryker®
Neurovascular

DECLARATION OF CONFORMITY

Legal Manufacturer:	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA 94538 USA
Manufacturing Site(s):	Stryker Neurovascular 2405 West Orton Circle West Valley City, Utah 84119 USA Or Stryker Neurovascular 4870 West 2100 South Salt Lake City, UT 84120 USA
European Representative:	Stryker European Operations B.V. Herikerbergweg 110 Amsterdam 1101 CM Netherlands
Product:	Synchro® Guidewires *Design Dossier NV00015269*
Product Category:	Guidewires
Classification:	Class III, Rule 7 according to Annex IX of the MDD

stryker®
Neurovascular

We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Notified Body:	BSI Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom CE Identification CE 0086
Quality Certificate:	BSI EN ISO 13485 Certificate # MD 638383 First issued 23 November 2015
EC Certificate:	BSI Certificate # CE 635352 First issued 01 June 2015
DE Certificate:	BSI Certificate # CE 637956 First issued 18 December 2015

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Neurovascular

Signature, Date of Issue:

Signature: Katherine Mack **Date:** Mar. 21, 2018
Katherine Mack
Senior Director of Quality Assurance
Stryker Neurovascular

Signature: Jennifer Mateus **Date:** March 21, 2018
Jennifer Mateus
Senior Director of Regulatory Affairs
Stryker Neurovascular

stryker®
Neurovascular

Attachment to the EC Declaration of Conformity for the Synchro Guidewires

UPN Number	Description
M00313010	Synchro® -14, .014" guidewire, 200 cm length, 35 cm tip
M00313020	Synchro® -14, .014" guidewire, 200 cm length, 45 cm tip
M00313310	Synchro® -14, .014" guidewire, 300 cm length, 35 cm tip
M00313320	Synchro® -14, .014" guidewire, 300 cm length, 45 cm tip
M00313410	Synchro® -14S, .014" guidewire, 200 cm length, 35 cm tip
M00316310	Synchro® -10, .010" guidewire, 200 cm length, 55 cm tip
M00316330	Synchro® -10, .010" guidewire, 300 cm length, 55 cm tip

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 637954**

Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

In respect of:

Synchro²® and Synchro SELECT™ guidewires

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-12-18** Date: **2020-11-19** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 637954

Issued To:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
M00326010	Synchro^2 Guidewire	0.014, 200cm, Soft	The Synchro^2 Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.	Class III
M00326110	Synchro^2 Guidewire	0.014, 200cm, Soft, Pre-Shaped		Class III
M00326310	Synchro^2 Guidewire	0.014, 300cm, Soft		Class III
M00326320	Synchro^2 Guidewire	0.014, 300cm, Soft, Pre-Shaped		Class III
M00326410	Synchro^2 Guidewire	0.014, 200cm, Standard		Class III
M00326420	Synchro^2 Guidewire	0.014, 200cm, Standard, Pre-Shaped		Class III
M00326510	Synchro^2 Guidewire	0.014, 300cm, Standard		Class III
M00326520	Synchro^2 Guidewire	0.014, 300cm, Standard, Pre-Shaped		Class III

First Issued: **2015-12-18** Date: **2020-11-19** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 637954

Issued To:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
S2SPS14215	Synchro^2 Guidewire	0.014, 215cm Support, Straight	The Synchro^2 Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.	Class III
S2SPS14300	Synchro^2 Guidewire	0.014, 300cm Support, Straight		Class III
S2SPP14215	Synchro^2 Guidewire	0.014, 215cm Support, Pre-Shaped		Class III
S2SPP14300	Synchro^2 Guidewire	0.014, 300cm Support, Pre-Shaped		Class III

First Issued: **2015-12-18** Date: **2020-11-19** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 637954

Issued To:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per the IFU	Classification
SSFT215STR	Synchro SELECT™	Soft Straight, 215cm length	The Synchro SELECT™ Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.	Class III
SSFT215PRE	Synchro SELECT™	Soft Pre-shaped, 215cm length		Class III
SSFT300STR	Synchro SELECT™	Soft Straight, 300cm length		Class III
SSFT300PRE	Synchro SELECT™	Soft Pre-shaped, 300cm length		Class III
SSTD215STR	Synchro SELECT™	Standard Straight, 215cm length		Class III
SSTD215PRE	Synchro SELECT™	Standard Pre-shaped, 215cm length		Class III
SSTD300STR	Synchro SELECT™	Standard Straight, 300cm length		Class III

First Issued: **2015-12-18** Date: **2020-11-19** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 637954

Issued To:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per the IFU	Classification
SSTD300PRE	Synchro SELECT™	Standard Pre-shaped, 300cm length	The Synchro SELECT™ Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.	Class III
SSUP215STR	Synchro SELECT™	Support Straight, 215cm length		Class III
SSUP215PRE	Synchro SELECT™	Support Pre-shaped, 215cm length		Class III
SSUP300STR	Synchro SELECT™	Support Straight, 300cm length		Class III
SSUP300PRE	Synchro SELECT™	Support Pre-shaped, 300cm length		Class III

First Issued: **2015-12-18** Date: **2020-11-19** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 637954

Issued To:

Stryker Neurovascular
47900 Bayside Parkway
Fremont
California
94538
USA

Certificate History

Date	Reference Number	Action
18 December 2015	10156544	Transfer from another notified body and renewal.
04 April 2017	10169560	Changes to carton and labelling, and introduction of electronic IFUs in compliance with EU Regulation 207/2012.
26 February 2018	8876112	Relocate Synchro² guidewire manufacturing from Stryker (West Valley City, UT) to Stryker (Salt Lake City, UT).
25 January 2019	8366187	Traceable to NB 0086.
28 February 2020	9668582	Certificate Renewal. Addition of products table in supplementary information section. Approval of sterilization cycle 320 at the Sterigenics location in Salt Lake City, UT. Line Extension addition of the Synchro² Support guidewires.
Current	3279937	Addition of the Synchro SELECT™ guidewires.

First Issued: **2015-12-18** Date: **2020-11-19** Expiry Date: **2024-05-26**

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DECLARATION OF CONFORMITY

Legal Manufacturer:	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA 94538 USA
Manufacturing Site(s):	Stryker Neurovascular 4870 West 2100 South Salt Lake City, UT 84120 USA
European Representative:	Stryker European Operations B.V. Herikerbergweg 110 Amsterdam 1101 CM Netherlands
Product:	Synchro$^{2®}$ and Synchro SELECT™ Guidewires *Design Dossier NV00015270*
Product Category:	Guidewires
Classification:	Class III, Rule 7 according to Annex IX of the MDD

We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Notified Body:	BSI Say Building, John M. Keynesplein 9 1066 EP Amsterdam CE Identification CE 2797
Quality Certificate:	BSI EN ISO 13485 Certificate # MD 638383 First issued 23 November 2015
EC Certificates:	BSI Certificate # CE 635352 First issued 01 June 2015
DE Certificate:	BSI Certificate # CE 637954 First issued 18 December 2015

Signature, Date of Issue:

Signature: Katherine Mack *Electronically signed by: Katherine Mack Reason: I approve this document Date: Jan 21, 2021 11:09 PST* **Date:** 21-Jan-2021

Kathrine Mack
Senior Director of Quality Assurance
Stryker Neurovascular

Signature: Jennifer Mateus *Electronically signed by: Jennifer Mateus Reason: I approve this document Date: Jan 21, 2021 11:16 PST* **Date:** 21-Jan-2021

Jennifer Mateus
Senior Director of Regulatory Affairs
Stryker Neurovascular

Attachment to EC Declaration of Conformity for Synchro^2 and Synchro SELECT Guidewires:

UPN Number	Model /Description
M00326010	Synchro^2, .014" guidewire, 200cm, Soft
M00326110	Synchro^2, .014" guidewire, 200cm, Soft Pre-Shaped
M00326310	Synchro^2, .014" guidewire, 300cm, Soft
M00326320	Synchro^2, .014" guidewire, 300cm, Soft Pre-Shaped
M00326410	Synchro^2, .014" guidewire, 200cm, Standard
M00326420	Synchro^2, .014" guidewire, 200cm, Standard Pre-Shaped
M00326510	Synchro^2, .014" guidewire, 300cm, Standard
M00326520	Synchro^2, .014" guidewire, 300cm, Standard Pre-Shaped
S2SPS14215	Synchro^2, .014" guidewire, 215cm, Support Straight
S2SPS14300	Synchro^2, .014" guidewire, 300cm, Support Straight
S2SPP14215	Synchro^2, .014" guidewire, 215cm, Support Pre-Shaped
S2SPP14300	Synchro^2, .014" guidewire, 300cm, Support Pre-Shaped
SSFT215STR	Synchro SELECT, Soft Straight, 215cm length
SSFT215PRE	Synchro SELECT, Soft Pre-shaped, 215cm length
SSFT300STR	Synchro SELECT, Soft Straight, 300cm length
SSFT300PRE	Synchro SELECT, Soft Pre-shaped, 300cm length
SSTD215STR	Synchro SELECT, Standard Straight, 215cm length
SSTD215PRE	Synchro SELECT, Standard Pre-shaped, 215cm length
SSTD300STR	Synchro SELECT, Standard Straight, 300cm length
SSTD300PRE	Synchro SELECT, Standard Pre-shaped, 300cm length
SSUP215STR	Synchro SELECT, Support Straight, 215cm length
SSUP215PRE	Synchro SELECT, Support Pre-shaped, 215cm length
SSUP300STR	Synchro SELECT, Support Straight, 300cm length
SSUP300PRE	Synchro SELECT, Support Pre-shaped, 300cm length

NV00015277_AG Synchro2 and Synchro SELECT DoC

Final Audit Report 2021-01-21

Created:	2021-01-21
By:	debbie frazier (debbie.frazier@stryker.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAwa9pVKvih9-fRa9x5b00JQCGZ4dnaHhZ

"NV00015277_AG Synchro2 and Synchro SELECT DoC" History

Document created by debbie frazier (debbie.frazier@stryker.com)
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2021-01-21 - 7:04:49 PM GMT

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2021-01-21 - 7:08:59 PM GMT- IP address: 71.202.54.94

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2021-01-21 - 7:16:01 PM GMT- IP address: 107.196.181.20

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Signature Date: 2021-01-21 - 7:16:15 PM GMT - Time Source: server- IP address: 107.196.181.20

Agreement completed.
2021-01-21 - 7:16:15 PM GMT

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 33363 rev. 2

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

Stryker Neurovascular
47900 Bayside Parkway,
FREMONT, CA 94538 UNITED STATES

pour les activités
for the activities

Conception, fabrication et distribution de dispositifs médicaux endovasculaires utilisés en neuroradiologie interventionnelle, cardiologie et radiologie interventionnelle périphérique

Design, manufacture and distribution of endovascular medical devices used for interventional neuroradiology, cardiology, and peripheral radiology procedures

réalisées sur le(s) site(s) de
performed on the location(s) of

Stryker Neurovascular
47900 Bayside Parkway, Fremont, CA 94538 - USA
Stryker Neurovascular
47421 Bayside Parkway, Fremont, CA 94538 - USA
Stryker Neurovascular
4870 West 2100 South, Salt Lake City, UT 84120 - USA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485:2016 & NF EN ISO 13485:2016

Début de validité */ Effective date :* **August 11th, 2020 (included)**
Valable jusqu'au */ Expiry date :* **February 28th, 2021 (included)**
Etabli le */ Issued on :* **August 11th, 2020**

On behalf of the President
Béatrice LYS
Technical Director

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

GMED N° 33363–2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 33363-1

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

Stryker Neurovascular
47900 Bayside Parkway,
Fremont, CA 94538 – USA
Conception / *Design*

****

Stryker Neurovascular
47421 Bayside Parkway, Fremont, CA 94538 – USA
Activités administrative / *Administrative activities*

****

Stryker Neurovascular
4870 West 2100 South, Salt Lake City, UT 84120 - USA
Développement, fabrication et distribution /
Development, manufacture and distribution

****

3 sites / *3 sites*

On behalf of the President
Béatrice LYS
Technical Director

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Implants and Instruments for Interventional Minimal Invasive Therapy according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	281863 MR2
Certificate unique ID	170773730
Effective date	2021-01-04
Expiry date	2024-05-26
Frankfurt am Main	2021-01-04

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Device family	Device	Class
Detachable Embolization Coils	Axium™ Helix	III
	Axium™ 3D	III
	Axium™ Nylon Helix	III
	Axium™ PGLA Helix	III
	Axium™ PGLA 3D	III
	Axium™ Prime Bare Platinum Helix	III
	Axium™ Prime Bare Platinum 3D	III
	Axium™ Prime Frame Complex	III
	Concerto™ Bare Platinum Helix	IIb
	Concerto™ Bare Platinum 3D	IIb
	Concerto™ PGLA Fiber Helix	III
	Concerto™ PGLA Fiber 3D	III
	Concerto™ Nylon Fiber Helix	IIb
Neurovascular Remodeling Devices	Solitaire™ AB Neurovascular Remodeling Device	III
	Pipeline™ Flex Embolization Device (PFED)	III
	Pipeline™ Flex Embolization Device with Shield Technology™ (SHIELD)	III
	Pipeline™ Vantage Embolization Device with Shield Technology™ (PED3)	III
Detachment Devices	Solitaire™ NDS-2x Detachment System	IIa
	Cable Set Sterile (NCS),	Is
	Solitaire Cable Set (CSS),	Is
	Instant Detacher (I.D.)	Is
	Artisse™ Detachment Device	IIa
Revascularization Devices	Solitaire™ 2 Revascularization Device	III
	Solitaire™ Platinum Revascularization Device	III
	Solitaire™ X Revascularization Device	III
Liquid Embolic Systems	Onyx™ Liquid Embolic System (LES)	III
Infusion Catheters	Cragg McNamara™ Catheter	IIb
	MicroMewi™ Infusion Catheter	IIb
Infusion Wires	ProStream™ Infusion Wire	IIb
Balloon Occlusion Catheters	HyperGlide™ Occlusion Balloon System	III
	HyperForm™ Occlusion Balloon System	III

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Device family	Device	Class
Syringe Adapters, Syringes and Introducer Sheaths	Echelon™ Syringe Adapter	Is
	Cadence™ Precision Injector Accessory	Is
	Onyx™ Syringe Catheter Interface Adapter	Is
	1mL Syringe	Is
Guide Wires	Mirage™ Hydrophilic Guidewire	III
	X-Pedion™ Hydrophilic Guidewire	III
	Avigo™ Hydrophilic Guidewire	III
Micro Catheters	Marksman™ Catheter	III
	Nautica™ Micro Catheter	III
	Echelon™ Micro Catheter	III
	Rebar™ Micro Catheter	III
	Orion™ Micro Catheter	III
	Phenom™ Catheter	III
Flow Directed Catheters	Marathon™ Flow Directed Micro Catheter	III
	Apollo™ Onyx™ Delivery Micro Catheter	III
Guide Catheter	Navien™ A+ Intracranial Catheter	III
	React™ 68 Catheter	III
	React™ 71 Catheter	III
	Rist™ Radial Access Selective Catheter	III
	Rist™ 079 Radial Access Guide Catheter	III
Surgical irrigation/aspiration system	Riptide™ Aspiraton Pump	IIa
	Riptide™ Large Bore Aspiration Tubing	Is
Embolization Devices	Artisse™ Intrasaccular Device	III

CERTIFICATE

This is to certify that the company

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Design, development, manufacture of infusion catheters, valved infusion catheters, infusion wires, hydrophilic stainless steel guidewires, guide catheters, occlusion balloon catheters, micro catheters, flow-directed micro catheters, liquid embolic systems, detachable embolic coils and detachment systems, embolization devices and detachment systems, syringes, neurovascular stents, injector and syringes for use with liquid embolic systems, neurovascular remodelling devices, vascular retrieval devices, neurovascular revascularization devices and aspiration systems.
Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	281863 MP2016
Certificate unique ID	170770269
Effective date	2020-12-01
Expiry date	2023-11-30
Frankfurt am Main	2020-11-23

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director
August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

Dr. Thomas Feldmann
Head of Certification Body

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 281863 MP2016
Certificate unique ID: 170770269
Effective date: 2020-12-01

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Location	Scope
Micro Therapeutics, Inc. **DBA ev3 Neurovascular** 5290 California Ave Irvine, CA 92617 United States of America	Design and development of infusion catheters, valved infusion catheters, infusion wires, hydrophilic stainless steel guidewires, guide catheters, occlusion balloon catheters, micro catheters, flow-directed micro catheters, liquid embolic systems, detachable embolic coils and detachment systems, embolization devices and detachment systems, syringes, neurovascular stents, injector and syringes for use with liquid embolic systems, neurovascular remodelling devices, vascular retrieval devices, neurovascular revascularization devices and aspiration systems.
Micro Therapeutics, Inc. **DBA ev3 Neurovascular** 9775 Toledo Way Irvine, CA 92618 United States of America	Design, development, manufacture and warehouse of infusion catheters, valved infusion catheters, infusion wires, hydrophilic stainless steel guidewires, guide catheters, occlusion balloon catheters, micro catheters, flow-directed micro catheters, liquid embolic systems, detachable embolic coils and detachment systems, embolization devices and detachment systems, syringes, neurovascular stents, injector and syringes for use with liquid embolic systems, neurovascular remodelling devices, vascular retrieval devices, neurovascular revascularization devices and aspiration systems.