Digitally signed by Kojevnikov Dmitrii
Date: 2019.03.28 15:58:24 IST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII **Nr.** 044647

Denumirea autorității de licențiere	**Camera de Licențiere**
Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență	**Societatea Comercială „OXIVIT-MED" S.R.L.** mun.Chișinău, bd. Decebal, 82, ap. 90
Data și numărul certificatului de înregistrare de stat a titularului de licență	30.07.2007 MD 0067985
Numărul de înregistrare a întreprinderii sau IDNO	1007600044280
Codul fiscal	
Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența	*** Importul și comercializarea dispozitivelor medicale ***
Data eliberării licenței	15 octombrie 2012
Valabilă pînă la Prelungită pînă la: 15.10.2022	15 octombrie 2017

Semnătura conducătorului autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

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

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

Funcţia, numele, prenumele persoanei care a eliberat certificatul

semnătura

MD 0067985

L.Ş.

„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **71** din **05.01.2016**

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 și codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;
2 Comerțul cu ridicata al parfumurilor și produselor cosmetice;
3 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerț cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerț cu ridicata;
7 Închirierea altor mașini și echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociați:
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 și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 05.01.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA · CAMERA ÎNREGISTRĂRII DE STAT Î.S. · 1004600077171 · 101

AA6 * EA * 0346843EA

c/f: 10037600044280; adresa: str. Independenței 28-34, 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	09723015012362

Data primirii 24.03.2019 21:40:54

Anexe la SNC
"Prezentarea situaţiilor financiare"
Aprobat de Ministerul Finanţelor al Republicii Moldova

SITUAŢIILE FINANCIARE

pentru perioada 01.01.2018 31.12.2018

Entitatea SC OXIVIT-MED SRL
(Denumirea completă)

40424951 (Cod CUIIO)

1007600044280 (Cod IDNO)

Sediul: MD MD-2024 (Cod poştal) MUN.CHIŞINĂU; MUN.CHIŞINĂU SEC.BOTANICA
Raionul (municipiul, UTA); Localitatea
Decebal, 82, , of.90
strada, nr, bl.

110 Cod CUATM

Activitatea principală: Comert cu amanuntul al articolelor medicale si ortopedice, in magazine specializate

G4774 Cod CAEM, rev.2

Forma de proprietate: Proprietate privată

15 Cod CFP

Forma organizatorico-juridică: SOCIETATI CU RASPUNDERE LIMITATA

530 Cod CFOJ

Date de contact: Tel. +37322808002 e-mail oxivit.medical@gmail.com

WEB:

Numele şi coordonatele al contabilului-şef: Dl (dna) Kojevnikov Dmitrii

Tel. +37369200333

Unitatea de măsură: leu

Anexa 8

Notă informativă privind veniturile şi cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	32.606.761	43.289.243
Alte venituri din activitatea operaţională	020		209.007
Venituri din alte activităţi	030	1.316.819	1.171.806
Total venituri (rd.010 + rd.020 + rd.030)	040	33.923.580	44.670.056
Variaţia stocurilor	050		
Costul vînzărilor mărfurilor vîndute	060	22.812.507	33.465.025
Cheltuieli privind stocurile	070		
Cheltuieli cu personalul privind remunerarea muncii	080	36.000	71.355
Contribuţii de asigurări sociale de stat obligatorii şi prime de asigurare obligatorie de asistenţă medicală	090	9.900	18.700
Cheltuieli cu amortizarea şi deprecierea activelor imobilizate	100		2.139
Alte cheltuieli	110	504.232	298.104
Cheltuieli din alte activităţi	120	1.421.291	820.441
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	24.783.930	34.675.764
Profit (pierdere) pînă la impozitare (rd.040 – rd.130)	140	9.139.650	9.994.292
Cheltuieli privind impozitul pe venit	150	1.102.843	1.203.230
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	8.036.807	8.791.062

Anexa 1

BILANȚUL

la 31.12.2018

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul perioadei de gestiune
1	2	3	4	5
1.	**Active imobilizate**			
	Imobilizări necorporale	010	3.087	2.437
	Imobilizări corporale în curs de execuție	020		
	Terenuri	030		
	Mijloace fixe	040	5.213	3.724
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiții financiare pe termen lung în părți neafiliate	070		
	Investiții financiare pe termen lung în părți afiliate	080		
	Investiții imobiliare	090		
	Creanțe pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	Total active imobilizate (rd.010 + rd.020 + rd.030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	8.300	6.161
2.	**Active circulante**			
	Materiale	140	1.086	1.101
	Active biologice circulante	150		
	Obiecte de mică valoare și scurtă durată	160		
	Producția în curs de execuție și produse	170		
	Mărfuri	180	2.038.858	5.035.582
	Creanțe comerciale	190	4.229.294	6.398.231
	Creanțe ale părților afiliate	200		
	Avansuri acordate curente	210	1.072.041	2.409.388
	Creanțe ale bugetului	220	392.255	477.973
	Creanțe ale personalului	230		
	Alte creanțe curente	240		
	Numerar în casierie și la conturi curente	250	6.594.078	7.745.065
	Alte elemente de numerar	260		
	Investiții financiare curente în părți neafiliate	270		
	Investiții financiare curente în părți afiliate	280		
	Alte active circulante	290	6.982	8.782
	Total active circulante (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	14.334.594	22.076.122
	Total active (rd.130 + rd.300)	310	14.342.894	22.082.283

Nr. cpt.	P A S I V	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul perioadei de gestiune
1	2	3	4	5
3.	**Capital propriu**			
	Capital social şi suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecţii ale rezultatelor anilor precedenţi	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	350	9.284.141	5.279.874
	Profit net (pierdere netă) al perioadei de gestiune	360	X	8.791.062
	Profit utilizat al perioadei de gestiune	370	X	
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	9.289.541	14.076.336
4.	**Datorii pe termen lung**			
	Credite bancare pe termen lung	400		
	Împrumuturi pe termen lung	410	76.630	76.630
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440	76.630	76.630
5.	**Datorii curente**			
	Credite bancare pe termen scurt	450		
	Împrumuturi pe termen scurt	460		
	Datorii comerciale	470	4.314.663	7.450.519
	Datorii faţă de părţile afiliate	480		
	Avansuri primite curente	490	219.377	337.734
	Datorii faţă de personal	500	2.054	14.819
	Datorii privind asigurările sociale şi medicale	510		
	Datorii faţă de buget	520	348.444	62
	Venituri anticipate curente	530		
	Datorii faţă de proprietari	540		
	Finanţări şi încasări cu destinaţie specială curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	92.185	126.183
	Total datorii curente (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	4.976.723	7.929.317
	Total pasive (rd.390 + rd.440 + rd.580)	590	14.342.894	22.082.283

Anexa 2

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2018 **pînă la** 31.12.2018

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	32.606.761	43.289.243
Costul vînzărilor	020	22.812.507	33.465.025
Profit brut (pierdere brută) (rd.010 – rd.020)	030	9.794.254	9.824.218
Alte venituri din activitatea operațională	040		209.007
Cheltuieli de distribuire	050	21.620	19.868
Cheltuieli administrative	060	475.577	337.477
Alte cheltuieli din activitatea operațională	070	52.935	32.953
Rezultatul din activitatea operațională: profit (pier-dere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	9.244.122	9.642.927
Rezultatul din alte activități: profit (pierdere)	090	-104.472	351.365
Profit (pierdere) pînă la impozitare (rd.080 + rd.090)	100	9.139.650	9.994.292
Cheltuieli privind impozitul pe venit	110	1.102.843	1.203.230
Profit net (pierdere netă) al perioadei de gestiune (rd.100 – rd.110)	120	8.036.807	8.791.062

Anexa 3

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2018 **pînă la** 31.12.2018

Nr. d/o	Indicatori	Cod rd.	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrşitul perioadei de gestiune
1	2	3	4	5	6	7
1	**Capital social şi suplimentar**					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevărsat	030	()	()	()	()
	Capital neînregistrat	040				
	Capital retras	050	()	()	()	()
	Total capital social şi suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5.400			5.400
2	**Rezerve**					
	Capital de rezervă	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total reserve (rd.070 + rd.080 + rd.090)	100				
3	**Profit nerepartizat (pierdere neacoperită)**					
	Corecţii ale rezultatelor anilor precedenţi	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	120	9.284.141		4.004.267	5.279.874
	Profit net (pierdere netă) al perioadei de gestiune	130	X	8.791.062	0	8.791.062
	Profit utilizat al perioadei de gestiune	140	X	()	()	()
	Rezultatul din tranziţia la noile reglementări contabile	150				
	Total profit nerepartizat (pierdere neacoperită) (rd.110 + rd.120 + rd.130 + rd.140 + rd.150)	160	9.284.141	8.791.062	4.004.267	14.070.936
4	**Alte elemente de capital propriu, din care**	170				
	Diferenţe din reevaluare	171				
	Subvenţii entităţilor cu proprietate publică	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180	9.289.541	8.791.062	4.004.267	14.076.336

Anexa 4

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2018 **pînă la** 31.12.2018

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operaţională			
Încasări din vînzări	010	31.819.317	44.233.939
Plăţi pentru stocuri şi servicii procurate	020	22.463.069	34.177.570
Plăţi către angajaţi şi organe de asigurare socială şi medicală	030	72.040	89.849
Dobînzi plătite	040		
Plata impozitului pe venit	050	767.369	2.090.569
Alte încasări	060		
Alte plăţi	070	2.973.220	6.763.644
Fluxul net de numerar din activitatea operaţională (rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070)	080	5.543.619	1.112.307
Fluxuri de numerar din activitatea de investiţii			
Încasări din vînzarea activelor imobilizate	090		
Plăţi aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
Alte încasări (plăţi)	130		
Fluxul net de numerar din activitatea de investiţii (rd.090 – rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite şi împrumuturi	150		
Plăţi aferente rambursării creditelor şi împrumuturilor	160		
Dividende plătite	170		
Încasări din operaţiuni de capital	180		
Alte încasări (plăţi)	190		
Fluxul net de numerar din activitatea financiară (rd.150 – rd.160 – rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	5.543.619	1.112.307
Diferenţe de curs valutar favorabile (nefavorabile)	220	-918.567	38.680
Sold de numerar la începutul perioadei de gestiune	230	1.969.026	6.594.078
Sold de numerar la sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	6.594.078	7.745.065

Anexa 6

Date generale

1. Certificat de înregistrare a entităţii, eliberat de Camera Înregistrării de Stat.

Număr de înregistrare _____ Data înregistrării _____ Seria _____ Număr _____

2. Capital social înregistrat de Camera Înregistrării de Stat:

data _____ ,suma _____ lei, inclusiv:

1) cota statului _____ lei,

2) cota deţinătorilor a cel puţin 20% _____ lei,

Modificări ulterioare:

a) _____ , suma _____ lei, inclusiv cota statului _____ lei,

b) _____ , suma _____ lei, inclusiv cota statului _____ lei,

3. Entităţile, activitatea cărora necesită licenţă, indică:

Licenţa în vigoare:

) Număr _____ ,data eliberării _____

Termen de valabilitate _____

Tipul de activitate _____

Organul care a eliberat licenţa _____

4. Numărul mediu scriptic al personalului în perioada de gestiune 1 persoane, inclusiv pe categorii:

1) personal administrativ 1 persoane,

2) muncitori _____ persoane,

5. Numărul personalului la 31.12.2018 2 persoane.

6. Remunerarea personalului entităţii în perioada de gestiune 71.355 lei.

7. Remunerarea membrilor organelor de administrare, de conducere şi supraveghere şi alte angajamente apărute sau asumate în legătură cu pensiile membrilor actuali sau ale foştilor membri ai acestor organe, pe categorii _____ lei.

8. Avansurile şi creditele acordate membrilor organelor specificate la pct.7 _____ lei, inclusiv rambursate _____ lei.

9. Valoarea activelor imobilizate şi circulante, înregistrate în calitate de gaj[1]

1) valoarea de gaj _____ lei,

2) valoarea contabilă _____ lei.

10. Numărul acţiunilor ordinare la finele perioadei de gestiune _____ unităţi.

11. Profit net (pierdere netă) a perioadei de gestiune pentru o acţiune ordinară:

1) profit _____ lei,

2) pierdere _____ lei.

12. Dividende calculate pentru o acţiune ordinară pentru perioada de gestiune:

1) plătite _____ lei,

2) planificate pentru plată _____ lei.

13. Valută străină disponibilă, recalculată în monedă naţională a Republicii Moldova – total _____ lei, inclusiv (lei, denumirea şi codul valutei):

) _____ codul valutei _____

14. Numerar legat – total _____ lei.

În rîndurile, în care se înscriu sumele de gaj, în toate coloanele prin fracţie se reflectă:

a) la numărător – valoarea de gaj;

b) la numitor – valoarea contabilă

_____

Anexa 7

Informaţiile privind activele imobilizate

de la 01.01.2018 **pînă la** 31.12.2018

Indicatori	Nr. rind	Existenţa la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieşirea în cursul perioadei (la costul de intrare)	Existenţa la sfîrşitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrşitul perioadei	Deprecierea acumulată la sfîrşitul perioadei
1		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuţie	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200	3.250	163				3.250	813	
2.1 brevete şi mărci	210								
2.2. licenţe de activitate	220								
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuţie	300								
4. Terenuri	400		x					x	
5. Mijloace fixe, total din care:	**500**	**11.916**	**6.703**				**11.916**	**8.192**	
5.1. clădiri	510								
5.2. construcţii speciale	520								
5.3. maşini, utilaje, instalaţii de transmisie	530								
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente şi inventar	550								
5.6. costuri ulterioare aferente obiectelor neînregistrate în bilanţ	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590	11.916	6.703				11.916	8.192	
6. Resurse minerale	**600**								
7. Investiţii imobiliare, total	**700**								

Anexa 9

NOTĂ INFORMATIVĂ
privind relaţiile cu nerezidenţii

Tabelul 1

Creanţe, investiţii financiare şi datorii pe termen lung aferente *fondatorilor* nerezidenţi

Indicatori	Cod rd./ cod ţară	Sold la începutul perioadei de gestiune	Modificări în perioada de gestiune			Sold la sfîrşitul perioadei de gestiune
			Intrări/ majorări	Ieşiri/ diminuări	Diferenţe de curs valutar	
1	2	3	4	5	6	7
Creanţe şi investiţii financiare pe termen lung – total	**010**					
Creanţe comerciale, *inclusiv pe ţări:*	020					
Avansuri acordate, *inclusiv pe ţări:*	030					
Imprumuturi acordate şi creanţe privind leasingul financiar, *inclusiv pe ţări:*	040					
Alte creanţe şi investiţii financiare, *inclusiv pe ţări:*	050					
Datorii pe termen lung – total	060					
Datorii comerciale, *inclusiv pe ţări:*	070					
Avansuri primite, *inclusiv pe ţări:*	080					
Credite bancare, împrumuturi şi datorii privind leasingul financiar, *inclusiv pe ţări:*	090					
Alte datorii, *inclusiv pe ţări:*	100					

Tabelul 2

Creanţe, investiţii financiare şi datorii pe termen lung aferente nerezidenţilor, *cu excepţia fondatorilor*

Indicatori	Cod rd./ cod ţară	Sold la începutul perioadei de gestiune	Modificări în perioada de gestiune			Sold la sfîrşitul perioadei de gestiune
			Intrări/ majorări	Ieşiri/ diminuări	Diferenţe de curs valutar	
1	2	3	4	5	6	7
Creanţe şi investiţii financiare pe termen lung – total	**010**					
Creanţe comerciale, *inclusiv pe ţări:*	020					
Avansuri acordate, *inclusiv pe ţări:*	030					
Împrumuturi acordate şi creanţe privind leasingul financiar, *inclusiv pe ţări:*	040					
Depozite, *inclusiv pe ţări:*	050					
Alte creanţe şi investiţii financiare, *inclusiv pe ţări:*	060					
Datorii pe termen lung – total	**070**					
Datorii comerciale, *inclusiv pe ţări:*	080					
Avansuri primite, *inclusiv pe ţări:*	090					
Credite bancare, împrumuturi şi datorii privind leasingul financiar, *inclusiv pe ţări:*	100					
Alte datorii, *inclusiv pe ţări:*	110					

Tabelul 3

Creanţe, investiţii financiare şi datorii curente aferente *fondatorilor* nerezidenţi

Indicatori	Cod rd./ cod ţară	Sold la începutul perioadei de gestiune		Modificări în perioada de gestiune				Sold la sfîrşitul perioadei de gestiune	
		La care termenul de plată nu a sosit sau este expirat pînă la un an	Termenul expirat mai mult de un an	Intrări/majorări		Ieşiri/ diminuări	Diferenţe de curs valutar	La care termenul de plată nu a sosit sau este expirat pînă la un an	Termenul expirat mai mult de un an
				Total	Transferări din active şi datorii pe termen lung în active şi datorii curente				
1	2	3	4	5	6	7	8	9	10
Creanţe şi investiţii financiare curente – total	010								
Creanţe comerciale, *inclusiv pe ţări:*	020								
Avansuri acordate, *inclusiv pe ţări:*	030								
Împrumuturi acordate şi creanţe privind leasingul financiar, *inclusiv pe ţări:*	040								
Alte creanţe şi investiţii financiare, *inclusiv pe ţări:*	050								
Datorii curente – total	**060**								
Datorii comerciale, *inclusiv pe ţări:*	070								
Avansuri primite, *inclusiv pe ţări:*	080								
Credite bancare, împrumuturi şi datorii privind leasingul financiar, *inclusiv pe ţări:*	090								
Datorii privind dividendele calculate, *inclusiv pe ţări:*	100								
Alte datorii, *inclusiv pe ţări:*	110								

Tabelul 4

Creanţe, investiţii financiare şi datorii curente aferente nerezidenţilor, *cu excepţia fondatorilor*

Indicatori	Cod rd./ cod ţară	Sold la începutul perioadei de gestiune		Modificări în perioada de gestiune				Sold la sfîrşitul perioadei de gestiune	
		La care termenul de plată nu a sosit sau este expirat pînă la un an	Termenul expirat mai mult de un an	Intrări/majorări		Ieşiri/ diminuări	Diferenţe de curs valutar	La care termenul de plată nu a sosit sau este expirat pînă la un an	Termenul expirat mai mult de un an
				Total	Transferări din active şi datorii pe termen lung în active şi datorii curente				
1	2	3	4	5	6	7	8	9	10
Creanţe şi investiţii financiare curente – total	010								
Creanţe comerciale, *inclusiv pe ţări:*	020								
Avansuri acordate, *inclusiv pe ţări:*	030								
Împrumuturi acordate şi creanţe privind leasingul financiar, *inclusiv pe ţări:*	040								
Depozite, *inclusiv pe ţări:*	050								
Alte creanţe şi investiţii financiare, *inclusiv pe ţări:*	060								
Datorii curente – total	**070**								
Datorii comerciale, *inclusiv pe ţări:*	080								
Avansuri primite, *inclusiv pe ţări:*	090								
Credite bancare, împrumuturi şi datorii privind leasingul financiar, *inclusiv pe ţări:*	100								
Alte datorii, *inclusiv pe ţări:*	110								

Tabelul 5

Investiţii financiare în străinătate şi participarea nerezidenţilor în capitalul social

Indicatori	Cod rd./ cod țară	Sold la începutul perioadei de gestiune	Intrări/ majorări	Ieşiri/ diminuări	Sold la sfîrşitul perioadei de gestiune
1	2	3	4	5	6
Investiţii financiare	010				
Cote de participaţie şi acţiuni de pînă la 10% inclusiv, în capitalul social al entităţilor nerezidente, *inclusiv pe ţări:*	020				
Cote de participaţie şi acţiuni de peste 10% în capitalul social al entităţilor nerezidente, *inclusiv pe ţări:*	030				
Capital social	040				
Cote de participaţie şi acţiuni de pînă la 10% inclusiv, *inclusiv pe ţări:*	050				
Cote de participaţie şi acţiuni de peste 10%, *inclusiv pe ţări:*	060				

Tabelul 7

Bunuri ale nerezidenţilor înregistrate în conturi extrabilanţiere

Indicatori	Cod rd./ cod țară	Sold la începutul perioadei de gestiune	Intrări/ diminuări	Ieşiri/ micşorări	Sold la sfîrşitul perioadei de gestiune
1	2	3	4	5	6
Bunuri primite în baza contractelor de comision, *inclusiv pe ţări*	010				
Bunuri primite spre prelucrare, *inclusiv pe ţări*	020				
Bunuri obţinute din materialele prelucrate, *inclusiv pe ţări*	030				

Tabelul 6

Venituri şi cheltuieli aferente tranzacţiilor cu nerezidenţii

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri – total	010		
Venituri aferente bunurilor procurate şi vîndute peste hotare fără trecerea frontierei de stat a Republicii Moldova, *inclusiv pe ţări:*	020		
Venituri din dobînzi aferente activităţii operaţionale şi altor activităţi, *inclusiv pe ţări:*	030		
Venituri din dividende şi participaţii în alte entităţi, *inclusiv pe ţări:*	040		
Venituri din decontarea datoriilor cu termenul de prescripţie expirat, *inclusiv pe ţări:*	050		
Alte venituri, *inclusiv pe ţări:*	060		
Cheltuieli – total	070		
Cheltuieli aferente bunurilor procurate şi vîndute peste hotare fără trecerea frontierei de stat a Republicii Moldova, *inclusiv pe ţări:*	080		
Cheltuieli privind dobînzile, *inclusiv pe ţări:*	090		
Cheltuieli şi provizioane aferente creanţelor comerciale şi altor creanţe compromise, *inclusiv pe ţări:*	100		
Alte cheltuieli, *inclusiv pe ţări:*	110		

Persoanele responsabile de semnarea rapoartelor financiare ale entităţii*

---

* conform art.36 din Legea contabilităţii

Anexa nr.7 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A1911733 **din** / от 18.03.2019

1. Destinatar / Получатель

ACHIZITII PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
S.C. OXIVIT-MED S.R.L.	1007600044280
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Decebal bd. nr.82 of.90	0110-SEC.BOTANICA

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Автоматизированной Информационной Системы

La data emiterii prezentului certificat restanța la bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 02.04.2019

5. Autentificarea organului fiscal / Подтверждение налогового органа

ŞEF DDF BOTANICA — A. PROHNIȚCHI

Funcția/Должность — Semnătura/Подпись — Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: Gînga
Numele și prenumele/Фамилия и имя

MINISTERUL FINANȚELOR AL REPUBLICII MOLDOVA
IDNO 1006601001182
SERVICIUL FISCAL DE STAT
S6

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 18.03.2019 ora 11:11:52 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,65)

ORDIN DE PLATA nr. 26 | DATA EMITERII 28 03 2019 | TIP.DOC. 1

PLATITI 70000.00 LEI Saptezeci Mii lei 00 bani

PLATITOR (R) S.C. "OXIVIT-MED" S.R.L.
Cod IBAN MD44ML0000000022517295O3
CODUL FISCAL 1007600044280

PRESTATORUL PLATITOR suc. "Invest"
CODUL BANCII MOLDMD2X329

BENEFICIAR (R) Centrul pentru Achizi?ii Publice Centralizate in Sanatate
Cod IBAN MD23TRPCCC518430B01859AA
CODUL FISCAL 1016601000212

PRESTATORUL BENEFICIAR Ministerul Finantelor - Trezoreria de Stat
CODUL BANCII TREZMD2X

DESTINATIA PLATII /P102/70000,00 Pentru garanfia pentru oferta la procedura de achizitie publica nr. ocds-b3wdp1-MD-1550747874823 din 29.03.2019

TIPUL TRANSFERULUI NORMAL/URGENT: N

L.S.

CODUL TRANZACTIEI: 101
DATA PRIMIRII: 28 03 2019
DATA EXECUTARII: 28 03 2019 13:27:42

SEMNATURILE EMITENTULUI

SEMNATURA PRESTATORU

B.C. «MOLDINDCONBANK» S.A.
mun. Chişinău
EX 28 martie 2019
MD-2012, Republica Moldova,
mun. Chişinău, str. Armenească, 38.

Digitally signed by Extras
Date: 2019.03.28 14:09:30 +02:00
Reason: MICB Extract
Location: Moldova Chisinau

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Perflow Medical Ltd.

24 Raoul Wallenberg St.
Tel Aviv 6971921
Israel

that the design of the following device(s)

Cascade™ M
Cascade™ L

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 513722 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:	CD0109 Cascade Technical file TOC Rev01 dated 2018-03-31 Further basis for the examination is referenced in the examination report and relating documents mentioned below.
Examination report:	411_18e_Report_TFR_Cascade_V1.doc dated 2018-05-28 The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	539670 MRA
Certificate unique ID	170714128
Effective date	2018-05-28
Expiry date	2023-05-27
Frankfurt am Main	2018-05-28

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.

EC Certificate - Full Quality Assurance System

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

No. **CE 684995**

Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Design, Development and Manufacture of Sterile Self-Expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents; Support Catheters; and Percutaneous Transluminal Angioplasty Catheters.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-12-20** Date: **2018-07-18** Expiry Date: **2020-12-16**

...making excellence a habit.™

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 684995**
Date:	**2018-07-18**
Issued To:	**ev3, Inc.** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
ev3, Inc. 2300 Berkshire Lane Plymouth Minnesota 55441 USA	**Design** **Development**
ev3, Inc. 3033 Campus Drive Plymouth Minnesota 55441 USA	**Regulatory Compliance**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 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 684995**
Date:	**2018-07-18**
Issued To:	**ev3, Inc.** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**EU Representative**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 684995**
Date: **2018-07-18**
Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
20 December 2017	8863804	First Issue – Transfer from another Notified Body.
Current	8907760	Adding Support Catheters and PTA Catheters to certificate scope per Notified Body transfer.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Perflow Medical Ltd.

24 Raoul Wallenberg St.
Tel Aviv 6971921
Israel

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:

Neurovascular thrombectomy devices and neurovascular remodeling devices 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.	513722 MR2
Certificate unique ID	170701523
Effective date	2018-06-19
Expiry date	2023-06-18
Frankfurt am Main	2018-05-28

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.: 513722 MR2
Certificate unique ID: 170701523
Effective date: 2018-06-19

Perflow Medical Ltd.

24 Raoul Wallenberg St.
Tel Aviv 6971921
Israel

Device family	Device	Class
Neurovascular thrombectomy device	Stream™	III
	Stream™ XL	III
Neurovascular remodeling device	Cascade ™ M	III
	Cascade ™ L	III

MAC's MEDICAL SURGICAL S.R.L.
CUI: RO 31275303
ORC:J35/495/2013
Bd. Eroilor de la Tisa nr. 45 , Timisoara,ROMANIA
Tel. +40727 399 598
Fax +40356 176 346
email : lucian.b@macsmedical.eu
Cont Trezorerie : RO74TREZ6215069XXX017408
Cont bancar : RO52DAFB102700245901RO01
http://www.macsmedical.eu

Catre: **OXIVIT-MED**
In attn: Bld.Moscova 14/1
Adresa: Chisinau

OFERTA NR: 25

Data: 25.03.2019

Nr. crt.	Cod	Descrierea produsului	Cantitate	u.m.	Pret (fara TVA) /u.m.	Discount	Total (fara TVA)	Valoare TVA (19%)	Total Euro (TVA inclus)
1	FG0001	Stream XL - Precise Manipulation braid length 36 mm / shaft lenght 190 cm	1.00	Buc	2500	15%	2125	403.75	2,528.75
2	FG0002	Stream - Precise Manipulation braid length 31 mm / shaft lenght 190 cm	1.00	Buc	2500	15%	2125	403.75	2,528.75
3	FG0005	Cascade L - Predictable Support braid length 35 mm / shaft lenght 190 cm	1.00	Buc	1980	15%	1683	319.77	2,002.77
4	FG0006	Cascade M - Predictable Support braid length 35 mm / shaft lenght 190 cm	1.00	Buc	1980	15%	1683	319.77	2,002.77

Total fara TVA: EUR 7,616.00
Valoare TVA: EUR 1,447.04

TOTAL: EUR 9,063.04

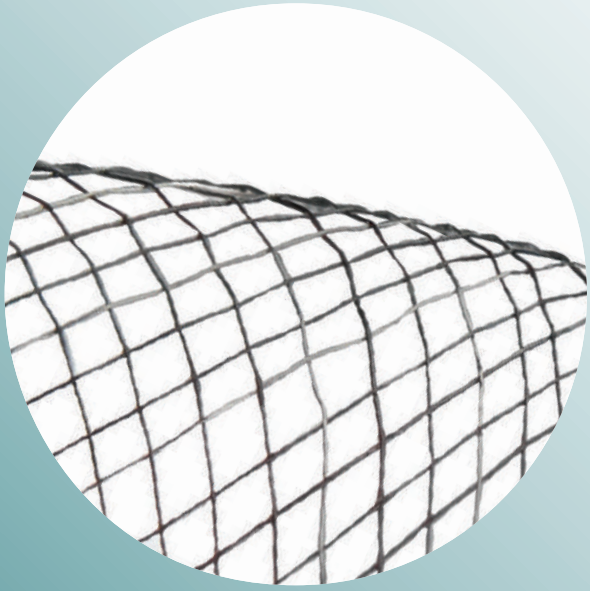
Termen de plata: 60 de zile
Termen de livrare: 4-6 saptamani
Tara de origine: Israel
Valabilitatea ofertei: 60 de zile

CASCADE™

Non-Occlusive Remodeling Net

Confident Control

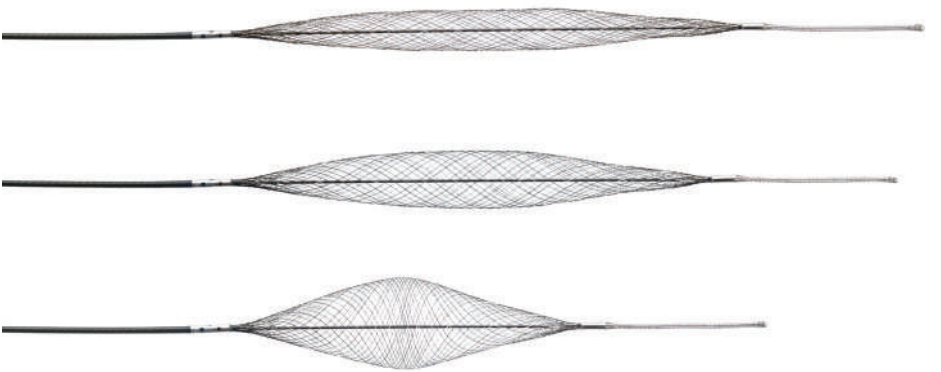
PERFLOW MEDICAL



The Cascade™ Net empowers physicians with non-occlusive support, full device control and excellent visibility during coil embolization of intracranial aneurysms.

Innovative tools for neurovascular interventions

The Cascade device features CEREBRAL NET™ technology, an adjustable braided net configuration that allows device manipulation for complex neurovascular conditions.



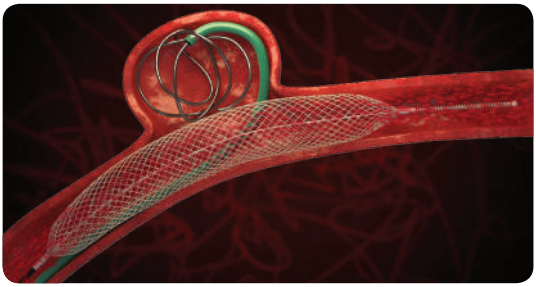
FULL CONTROL UNDER YOUR COMMAND

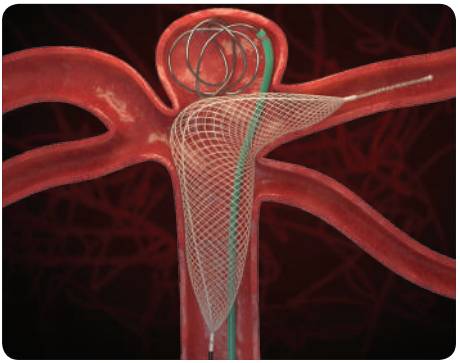
Make real-time informed decisions to improve patient outcomes.

OPTIMIZE COMPLIANCE

Responsive braided net provides excellent compliance with vessel geometry.

Focus on Repair





Support with Perfusion
Cascade keeps coils in place while enabling blood flow through the device.

Treatment Centered
Cascade does not limit the procedure time allowing to safely treat the aneurysm.

A Perfect Balance
The right balance between rigidity and flexibility provides a straight non-contorted shape.

Architectural Edge

Optimized Cell Size

Densely braided net creates a physical barrier that prevents coil protrusion and possible entanglement.

Evenly Distributed Radial Force

Thin wires provide compliance with vessel geometry and no pressure points on the artery wall.

Predictable Support

Operator manipulations correspond to expected behavior of the braided net.

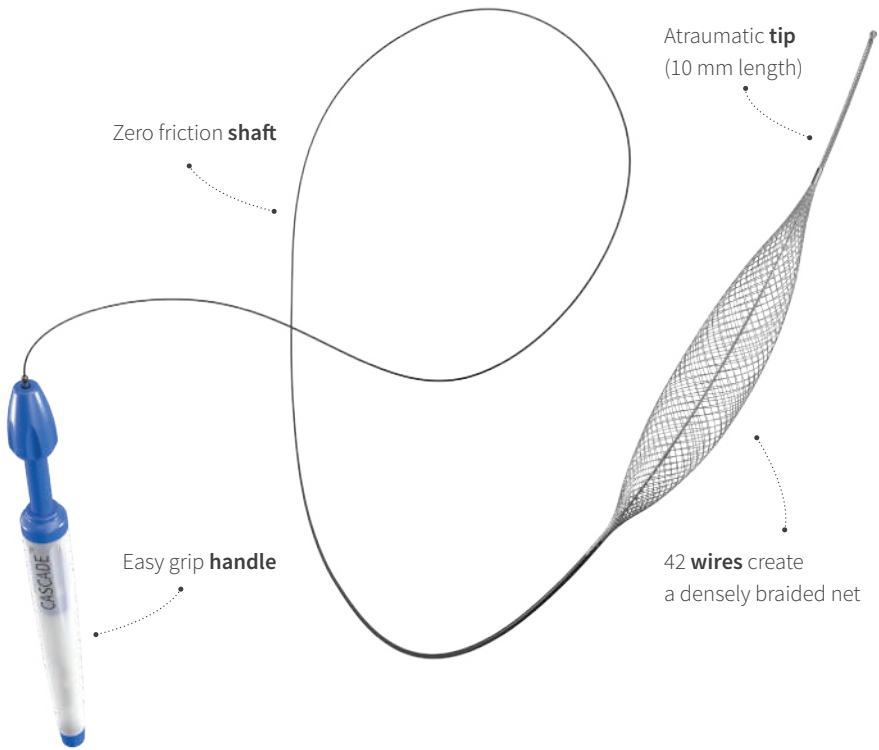
Reliable and Adaptable

Adjust length by partially re-sheathing the net with a microcatheter.

Excellent Radiopacity

The device is visible throughout the procedure.

The Cascade device is intended for use in vessel diameters of 2.0 – 6.0 mm



A perfect fit, every time

Model	*Catalog number*	*Maximal braid length*	*Actuation shaft length*	*Effective braid diameter*	*Recommended Vessel Diameter*	*Microcatheter Min ID*
Cascade M	FG0006	35 mm	190 cm	0.6-4 mm	2-4 mm	0.021”
Cascade L	FG0005			0.6-6 mm	4-6 mm	

PERFLOW MEDICAL

Empowering Physicians. Caring for Patients.

24 Raoul Wallenberg St., Tel Aviv 6971921, Israel
+972-3-6544011 **www.perflow.com**

CE 0297

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

Perflow products are not available for sale in the United States.

LB0015 Rev01

STREAM™

Dynamic Neuro-Thrombectomy Net

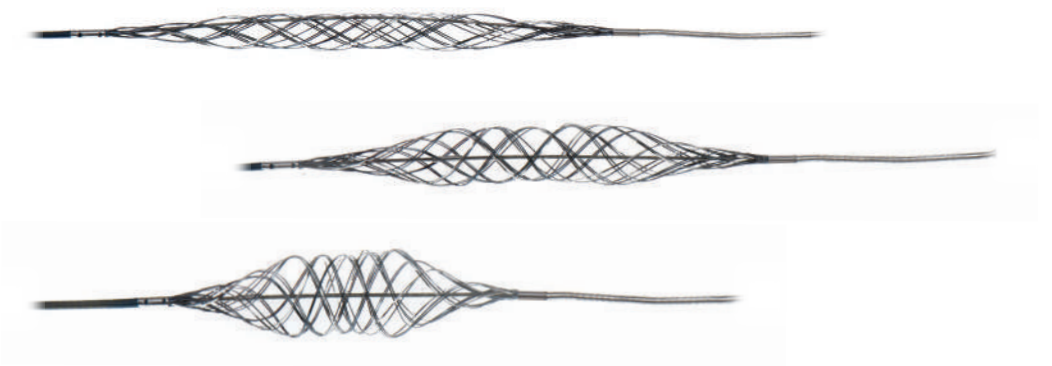
Perfecting Perfusion

PERFLOW MEDICAL

The Stream™ Net empowers physicians with full device control and excellent visibility to make real-time adjustments during a thrombectomy procedure.

Innovative tools for neurovascular interventions

The Stream device is the first product to feature CEREBRAL NET™ technology, an adjustable braided net configuration that allows device manipulation for complex neurovascular conditions.



TAKE CONTROL

Real-time adjustments

of net diameter, length, and radial force

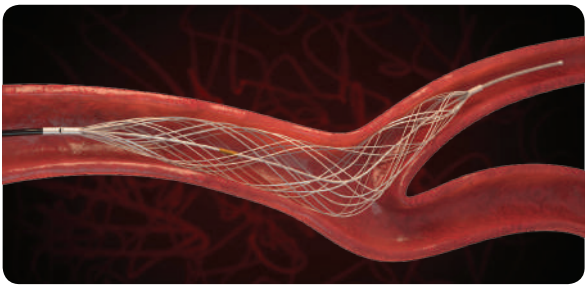
EXPAND YOUR OPTIONS

Physician-refined compliance

provides the best fit for the vessel

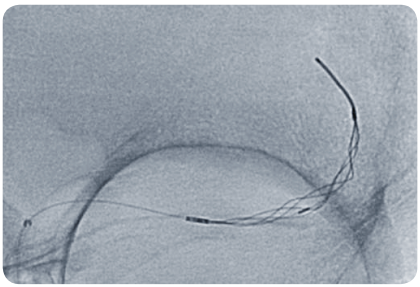
Apply Your Expertise in Real-time

Clinical adjustments that make a difference



Prevent Collapse in Tortuous Anatomy

Dynamic wall apposition with the ideal balance of flexibility and rigidity.



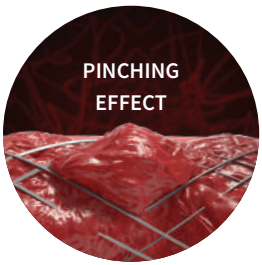
See the Complete Picture

Braided net with excellent visibility under fluoroscopy.

Secure the Thrombus

Efficient Clot Retention

The braided net employs three methods to securely anchor and capture the clot during retrieval.



Radial Force generates friction between the clot and the device grip.

Pinching Effect created by diameter adjustments that change the angle between net wires.

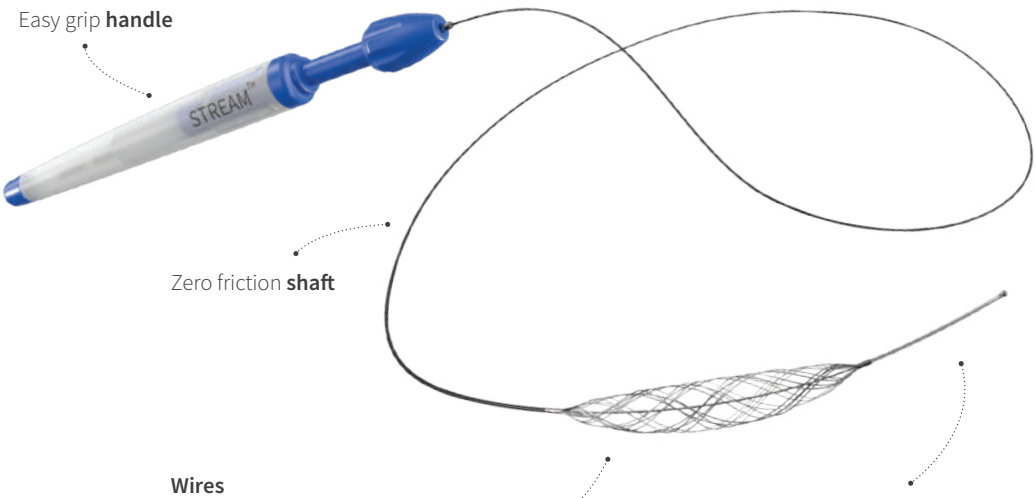
Cross-Wire Entanglement within overlapping braided wires ensnares the clot.

Precise Manipulation

The Stream's unique handle uses an intuitive and ergonomic design to translate forces while providing optimized tensile feedback.

- **Free mode** allows continuous adjustments.
- **Auto-lock mode** allows incremental adjustments.

The Stream devices are intended for use in vessel diameters of 1.5 – 6.0 mm



A perfect fit, every time

Device	*Catalog number*	*Maximal braid length*	*Actuation shaft length*	*Effective braid diameter*	*Recommended vessel diameter*	*Microcatheter Min ID*
Stream	FG0002	31 mm	190 cm	0.5-4.5 mm	1.5-4.5 mm	0.021”
Stream XL	FG0001	36 mm		0.5-6.0 mm	4.0-6.0 mm	

PERFLOW MEDICAL

Empowering Physicians. Caring for Patients.

24 Raoul Wallenberg St., Tel Aviv 6971921, Israel
+972-3-6544011 **www.perflow.com**

CE 0297

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

Perflow products are not available for sale in the United States.

LB0012 Rev01

EC Design Examination Certificate: Certificate US05/64921

ev3, Inc.

4600 Nathan Lane North,
Plymouth, MN, 55442, United States

Device Identification:

Protégé™ RX Self-Expanding Peripheral Stent System

Intended Purpose of Device:

Carotid - The stent is indicated for treatment of stenoses of the common carotid artery (CCA), internal carotid artery (ICA), and carotid bifurcation.

Peripheral - The stent is indicated for use in occlusions, lesions at high risk for abrupt closure or threatened closure following percutaneous transluminal angioplasty (PTA); or lesions believed to be at high risk for restenosis following PTA in the common iliac, external iliac, or subclavian arteries. Stenting is intended to improve and maintain artery luminal diameter.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 3 September 2015 until 11 March 2020
Issue 10

Certification is based on report number(s) WW/MC 212219 dated 2 August 2015

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum

Authorised by

SGS United Kingdom Limited, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS EC 01 0311

PERFLOW MEDICAL

DECLARATION OF CONFORMITY

Manufacturer:	Perflow Medical Ltd. 24 Raoul Wallenberg St. Tel Aviv, 6971921, Israel Tel: +972-3-6544011 Fax: +972-3-5546211	**Authorized representative:**	MEDNET GmbH Borkstrasse 10 48163 Münster, Germany Tel: +49-251 32266-0 Fax: +49-251 32266-22
Notified Body:	DQS Medizinprodukte GmbH 0297 August-Schanz-Str. 21, 60433 Frankfurt, Germany Tel: +49 69 95427-342 Fax: +49 69 95427-6342 www.dqs-med.de		
Conformity assessment procedure:	Annex II (Full Quality Assurance System) of the Medical Device Directive 93/42/EEC Main standards: EN ISO 13485:2016 EN ISO 14971:2012 Additional applicable standards are detailed in the Technical File		

Products:

Product name	Class	Annex	Product code	EC examination certificate	Valid until
Stream XL	III	II	FG0001	513722MRA	2020-12-21
Stream	III	II	FG0002	513722MRA	2020-12-21

We, Perflow Medical Ltd., hereby declare and are responsible to ensure that the above mentioned product(s) manufactured starting with December 2015 complies with the European Medical Device Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed in Tel Aviv: 20/6/18

Name and Authority: Danny Farin, CEO

Signature:

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	170716703
Effective date	2018-06-22
Expiry date	2021-10-31
Frankfurt am Main	2018-06-22

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: 170716703
Effective date: 2018-06-22

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
Detachment Devices	Solitaire™ NDS-2x Detachment System	IIa
	Artisse™ Detachment Device	IIa
	Cable Set sterile (NCS),	Is
	Solitaire Cable Set (CSS),	Is
	Instant Detacher (I.D.)	Is
Revascularization Devices	Solitaire™ 2 Revascularization Device	III
	Solitaire™ Platinum Revascularization Device	
	MindFrame Capture™ LP Revascularization Device	
Liquid Embolic Systems	Onyx™ Liquid Embolic System (LES)	
	Onyx® Aneurysm System (Onyx HD-500)	III

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170716703
Effective date: 2018-06-22

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

Device family	Device	Class
Surgical Instruments for Circulatory System	Alligator™ Retrieval Device – Neurovascular and Peripheral Application	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
Syringe Adapters, Syringes and Introducer Sheaths	Echelon™ Syringe Adapter	Is
	Cadence™ Precision Injector Accessory	Is
	Onyx™ Syringe Catheter Interface Adapter	Is
Guide Wires	Mirage™ Hydrophilic Guidewire	III
	Silverspeed™ 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
	Arc™/Arc™ Mini Intracranial Support Catheter	III
Flow Directed Catheters	Marathon™ Flow Directed Micro Catheter	III
	Ultraflow™ HPC Flow Directed Micro Catheter	III
	Apollo™ Onyx™ Delivery Micro Catheter	III

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170716703
Effective date: 2018-06-22

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

Device family	Device	Class
Guide Catheter System	Navien™ A+ Intracranial Catheter	III
Embolization Devices	Medina Embolization Device™	III
	Artisse™ Embolization Device	III

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

that the design of the following device(s)

Axium™ Prime Detachable Coil System

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: 4. STED16-005_Axium Prime.pdf dated 2017-01-18

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_Axium+Prime_V1.docx dated 2017-03-12

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	393599 MRA
Certificate unique ID	170679345
Effective date	2017-03-12
Expiry date	2022-03-11
Frankfurt am Main	2017-03-12

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.

411.23 Version 1.0

Annex to certificate
Certificate registration No.: 393599 MRA
Certificate unique ID: 170679345
Effective date: 2017-03-12

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

Axium™ Prime Detachable Coil System	Axium™ Prime Bare Platinum Helix Axium™ Prime Bare Platinum 3D Axium™ Prime Frame Complex

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

that the design of the following device(s)

Rebar™ and Nautica™ Micro Catheters

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Dessign Dossier_Rebar_Nautica_Re_Cert dated July 23, 2013

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: EN_370_1_3_Report_ECDE_Nautica_V1 dated 2013-11-18
EN_370_1_3_Report_ECDE_Nautica_V3 dated 2018-02-06

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	489932 MRA
Certificate unique ID	170707621
Effective date	2018-02-06
Expiry date	2018-12-17
Frankfurt am Main	2018-02-06

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.

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

that the design of the following device(s)

Navien A+ Intracranial Support Catheter

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: 3_TD13-025_NavienA+DesignDossier_Re-Cert_LineExtn_Final05MAR14 dated 2014-03-05

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: EN_370_1_3_Report_ECDE_Navien_V2 dated 2014-06-30

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration No.	499969 MRA
Certificate unique ID	170597484
Effective date	2014-07-13
Expiry date	2019-07-12
Frankfurt am Main	2014-07-13

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de

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

20120803/2/EN380310

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Micro Therapeutics, Inc.

d/b/a ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

that the design of the following device(s)

Solitaire™ Platinum Revascularization Device

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:

NV-STED Solitaire Platinum Revascularization Device 05FEB2016.pdf dated February 05, 2018
NV-STED Solitaire Platinum Revascularization Device 15AUG16.pdf dated 2016-09-14
NV-STED Solitaire Platinum Revascularization Device Rev. 5 pdf dated 2017-05-22
NV-STED Solitaire Platinum Revascularization Device rev. 6 dated 2018-06-11

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report:

2016-02-22+411_18e_Report_TFR_Solitaire+Platinum00 dated 2016-03-11
411_18e_Report_TFR_Solitaire Platinum dated 2016-09-16
411_18e_Report_TFR_Solitaire Platinum V03 dated 2017-07-26
411_18e_Report_TFR_Solitaire+Platinum+04 dated 2018-08-13

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	528000 MRA
Certificate unique ID	170721043
Effective date	2018-08-13
Expiry date	2021-03-04
Frankfurt am Main	2018-08-13

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.

EC Certificate Full Quality Assurance System: US00/51647.01

The management system of

ev3, Inc.

4600 Nathan Lane North,
Plymouth, MN, 55442, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2015 until 16 December 2020
And remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 December 2018
Issue 20. Certified since 17 June 2001

Certification is based on reports numbered WW/MC 201110

Multiple certificates have been issued for this scope
The main certificate is numbered US00/51647.00
This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

ev3, Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 20

Detailed scope

Sterile medical devices: Guidewires; Snares, Microsnares, Snare Catheters and Microcatheters; Endovascular Catheters; Rotating Y-Connectors; Thrombectomy Devices; Atherectomy Systems; Percutaneous Transluminal Angioplasty (PTA) Catheters; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices. Self-expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents, Crossing Catheters, Re-entry Catheters.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

3033 Campus Drive, Plymouth, MN, 55441, United States

EC Certificate - Full Quality Assurance System

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

No. **CE 77043**

Issued To: **Fuji Systems Corporation**
Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan

In respect of:

The design, development and manufacture of sterile intravascular occluding catheters and endotracheal tubing.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2003-09-19** Date: **2018-09-13** Expiry Date: **2023-09-18**

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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 77043**
Date:	**2018-09-13**
Issued To:	**Fuji Systems Corporation** **Shirakawa Plant** **200-2 Aza-Ohira,** **Odakura, Nishigo,** **Nishi Shirakawa Gun,** **Fukushima** **961-8061** **Japan**

Subcontractor:	**Service(s) supplied**
Dr. Hans-Joachim Lau Flughafenstrasse 52a (Building C) 22335 Hamburg Germany	**EU Representative**
Fuji Systems Corporation Shin-Shirakawa Plant 1-23 Tsukinoiri Kayane Shirakawa Fukushima 961-0004 Japan	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 77043**

Date: **2018-09-13**

Issued To: **Fuji Systems Corporation**
Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan

Date	Reference Number	Action
19 September 2003		First issue.
22 May 2008	7202874	Addition of Gastrostomy feeding balloon tube. Addition of Sengensten-Blackmore tubing and Linton Naclas tubing from CE 77715.
12 September 2008	7278861	Certificate renewal.
11 April 2011	7557229	Extension to scope to include Intravascular Catheters, addition of the EU Representatives details and update to manufacturers address to reference the Shirakawa Plant.
17 August 2012	7878109	Change of EU Representative from KRAUTH Medical KG to Dr. Hans-Joachim Lau.
12 September 2013	8034545	Certificate renewal.
Current	9640917	Certificate renewal. Update to certificate scope to remove nephrostomy catheters, urinary catheters, drainage catheters, tracheostomy tubing, gastrostomy feeding balloon tube, Sengstaken-Blakemore tubing and Linton Naclas tubing; sterile and non-sterile Trex gauze. Addition of subcontractor Fuji Systems Corporation Shin-Shirakawa Plant.

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 550009**

Issued To: **Fuji Systems Corporation**
Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan

In respect of:

Intravascular Catheter with Cuff

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **11 April 2011** Date: **01 April 2016** Expiry Date: **10 April 2021**

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bsi.

By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 550009

Issued To:

Fuji Systems Corporation
Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan

Product: Intravascular Catheter with Cuff

The following parameters apply to the family of products covered by this certificate:

Device Trade Name	Intravascular Occluding Catheter Variants				
	Catalogue Number(s)	Number of lumens	O.D. (mm)	Length Range (mm)	Size Range in French size (F)
CELLO	1610060, 1610070, 1610080, 1610090	2	2.00 -2.90	150 - 2000	6.0, 7.0, 8.0, 9.0

First Issued: **11 April 2011** Date: **01 April 2016** Expiry Date: **10 April 2021**

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By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 550009

Issued To:

Fuji Systems Corporation
Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan

Certificate History

Date	Reference Number	Action
11 April 2011	10117057	First issue
17 September 2014	10151155	Change scope of certificate from "Intravascular Balloon Occlusion Catheters" to "Intravascular Catheter with Cuff" to align with the DOC and Labelling.
01 April 2016	10161193	Certificate Renewal. Removal of trade names and product codes for IC OCCLUDER, SPF CATHETER, MASAMUNE and IIGUMAN.

First Issued: **11 April 2011** Date: **01 April 2016** Expiry Date: **10 April 2021**

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EC Certificate - Full Quality Assurance System

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

No. **CE 684995**

Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Design, Development and Manufacture of Sterile Self-Expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents; Support Catheters; and Percutaneous Transluminal Angioplasty Catheters.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-12-20** Date: **2018-07-18** Expiry Date: **2020-12-16**

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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 684995**
Date:	**2018-07-18**
Issued To:	**ev3, Inc.** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
ev3, Inc. 2300 Berkshire Lane Plymouth Minnesota 55441 USA	**Design** **Development**
ev3, Inc. 3033 Campus Drive Plymouth Minnesota 55441 USA	**Regulatory Compliance**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 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 684995**
Date:	**2018-07-18**
Issued To:	**ev3, Inc.** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 684995**
Date: **2018-07-18**
Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
20 December 2017	8863804	First Issue – Transfer from another Notified Body.
Current	8907760	Adding Support Catheters and PTA Catheters to certificate scope per Notified Body transfer.

***Document Number**: 10909697DOC*

REVISION HISTORY			
Rev.	**Date**	**Description**	**Filled By**
1	10/04/2018	First emission on new template	Anna Maria Selera
2	18/02/2019	QAS and QMS re-certification per MDD 93/42/EEC and EN ISO 13485:2016	Anna Maria Selera

***MANUFACTURER AS PER MDD 93/42/EEC**:* DOC/*SBI/07-03*

Invatec S.p.A.
Via Martiri della Libertà, 7
25030 Roncadelle (BS)
Italy

EC DECLARATION OF CONFORMITY

We, *Invatec S.p.A.*, hereby declare under sole liability that the product*(s)* as listed below *is(are)* in conformity to the provisions of the MDD 93/42/EEC, which apply to it.

Conformity assessment procedure: per MDD 93/42/EEC, Annex II, excluding section (4)

The product*(s) is(are)* currently supported by the following certificate:

EC Certificate for the Quality Assurance System (QAS) in accordance with Annex II, excluding section (4) of the MDD 93/42/EEC, N° 50251-16-09, emitted on 09/02/2019

QAS certificate validity period: from *16/02/2019* to *15/02/2024*

NOTIFIED BODY:
Dekra Certification GmbH, Handwerkstraße 15-D-70565 Stuttgart (Germany), with Notified Body ID number 0124.

PRODUCT*(S)* SUPPORTED BY THE ABOVE CERTIFICATE

Product name:	***Admiral Xtreme***
Product description:	PTA catheter
Product codes:	*Refer to Annex I*
Device classification per MDD 93/42/EEC (Annex IX):	II a

SIGNATURE *(on behalf of manufacturer)*:

Marco Brolis
Title: Regulatory Affairs Manager

PLACE AND DATE: Roncadelle, 18 FEB 2019

Annex I: « Admiral Xtreme » product codes

SBI030020080	SBI040300080	SBI060060080	SBI070100150
SBI030020130	SBI040300130	SBI060060130	SBI070120080L
SBI030040080	SBI050020080	SBI060060150	SBI070120130L
SBI030040130	SBI050020130	SBI060080080	SBI070120150
SBI030080080	SBI050020150	SBI060080130	SBI070150080L
SBI030080130	SBI050040080	SBI060080150	SBI070150130L
SBI030100080	SBI050040130	SBI060100080	SBI070150150
SBI030100130	SBI050040150	SBI060100130	SBI070200080L
SBI030120080	SBI050060080	SBI060100150	SBI070200130L
SBI030120130	SBI050060130	SBI060120080	SBI070200150
SBI040020080	SBI050060150	SBI060120130	SBI070250080
SBI040020130	SBI050080080	SBI060120150	SBI070250130
SBI040020150	SBI050080130	SBI060150080	SBI080020080
SBI040040080	SBI050080150	SBI060150130	SBI080020130
SBI040040130	SBI050100080	SBI060150150	SBI080040080
SBI040040150	SBI050100130	SBI060200080L	SBI080040130
SBI040060080	SBI050100150	SBI060200130L	SBI080060080
SBI040060130	SBI050120080	SBI060200150	SBI080060130
SBI040060150	SBI050120130	SBI060250080L	SBI080080080
SBI040080080	SBI050120150	SBI060250130L	SBI080080130
SBI040080130	SBI050150080	SBI060300080L	SBI090020080
SBI040080150	SBI050150130	SBI060300130L	SBI090020130
SBI040100080	SBI050150150	SBI070020080	SBI090040080
SBI040100130	SBI050200080	SBI070020130	SBI090040130
SBI040100150	SBI050200130	SBI070020150	SBI090060080
SBI040120080	SBI050200150	SBI070040080	SBI090060130
SBI040120130	SBI050250080	SBI070040130	SBI090080080
SBI040120150	SBI050250130	SBI070040150	SBI090080130
SBI040150080	SBI050300080L	SBI070060080	SBI100020080
SBI040150130	SBI050300130L	SBI070060130	SBI100020130
SBI040150150	SBI060020080	SBI070060150	SBI100040080
SBI040200080	SBI060020130	SBI070080080	SBI100040130
SBI040200130	SBI060020150	SBI070080130	SBI120020080
SBI040200150	SBI060040080	SBI070080150	SBI120020130
SBI040250080	SBI060040130	SBI070100080	SBI120040080
SBI040250130	SBI060040150	SBI070100130	SBI120040130

Document Number: ***10910094DOC***

REVISION HISTORY			
Rev.	**Date**	**Description**	**Filled By**
1	10/04/2018	First emission on new template	Anna Maria Selera
2	19/02/2019	Update of product codes (removal of RX codes) QAS and QMS re-certification per MDD 93/42/EEC and EN ISO 13485:2016	Anna Maria Selera

MANUFACTURER AS PER MDD 93/42/EEC:

Invatec S.p.A.
Via Martiri della Libertà, 7
25030 Roncadelle (BS)
Italy

DOC/*AMD/09*

EC DECLARATION OF CONFORMITY

We, *Invatec S.p.A.*, hereby declare under sole liability that the product*(s)* as listed below *is(are)* in conformity to the provisions of the MDD 93/42/EEC, which apply to it.

Conformity assessment procedure: per MDD 93/42/EEC, Annex II, excluding section (4)

The product*(s) is(are)* currently supported by the following certificate:

EC Certificate for the Quality Assurance System (QAS) in accordance with Annex II, excluding section (4) of the MDD 93/42/EEC, N° 50251-16-09, emitted on 09/02/2019

QAS certificate validity period: 16/02/2019 to *15/02/2024*

NOTIFIED BODY:
Dekra Certification GmbH, Handwerkstraße 15-D-70565 Stuttgart (Germany), with Notified Body ID number 0124.

PRODUCT*(S)* SUPPORTED BY THE ABOVE CERTIFICATE

Product name:	**Amphirion Deep**
Product description:	PTA catheter
Product codes:	*Refer to Annex I*
Device classification per MDD 93/42/EEC (Annex IX):	II a

SIGNATURE *(on behalf of manufacturer)*:

Marco Brolis
Title: Regulatory Affairs Manager

PLACE AND DATE:

Roncadelle, 19 FEB. 2019

Annex I: Amphirion Deep product codes

AMD 015 020 001	AMD 035 150 002	AMD 030 080 152
AMD 015 020 002	AMD 335 210 002	AMD 030 120 152
AMD 020 040 002	AMD 040 040 002	AMD 030 150 152
AMD 020 080 002	AMD 040 080 002	AMD 253 210 152
AMD 020 120 002	AMD 040 120 002	AMD 035 040 152
AMD 020 150 002	AMD 040 150 002	AMD 035 080 152
AMD 025 040 002	AMD 354 210 002	AMD 035 120 152
AMD 025 080 002	AMD 015 020 151	AMD 035 150 152
AMD 025 120 002	AMD 015 020 152	AMD 335 210 152
AMD 025 150 002	AMD 020 040 152	AMD 040 040 152
AMD 225 210 002	AMD 020 080 152	AMD 040 080 152
AMD 030 040 002	AMD 020 120 152	AMD 040 120 152
AMD 030 080 002	AMD 020 150 152	AMD 040 150 152
AMD 030 120 002	AMD 025 040 152	AMD 354 210 152
AMD 030 150 002	AMD 025 080 152	
AMD 253 210 002	AMD 025 120 152	
AMD 035 040 002	AMD 025 150 152	
AMD 035 080 002	AMD 225 210 152	
AMD 035 120 002	AMD 030 040 152	

Document Number: ***10910098DOC***

REVISION HISTORY			
Rev.	**Date**	**Description**	**Filled By**
1	10/04/2018	First emission on new template	Anna Maria Selera
2	19/02/2019	QAS and QMS re-certification per MDD 93/42/EEC and EN ISO 13485:2016	Anna Maria Selera

MANUFACTURER AS PER MDD 93/42/EEC:
Invatec S.p.A.
Via Martiri della Libertà, 7
25030 Roncadelle (BS)
Italy

DOC/*PCF/13*

EC DECLARATION OF CONFORMITY

We, *Invatec S.p.A.*, hereby declare under sole liability that the product*(s)* as listed below *is(are)* in conformity to the provisions of the MDD 93/42/EEC, which apply to it.

Conformity assessment procedure: per MDD 93/42/EEC, Annex II (4)

The product*(s) is(are)* currently supported by the following certificate*(s):*

EC Certificate for the Quality Assurance System (QAS) in accordance with Annex II, excluding section (4) of the MDD 93/42/EEC, N° *50251-16-09*, emitted on *09/02/2019*.

AND

EC Design Examination (DE) Certificate in accordance with Annex II (4) of the MDD *93/42/EEC, N° 50251-23-N5, emitted on 23/02/2018, (Annex Rev.0)*

QAS certificate validity period: from *16/02/2019* to *15/02/2024*
DE certificate validity period: from *16/02/2018* to *15/02/2023*

NOTIFIED BODY:
Dekra Certification GmbH, Handwerkstraße 15-D-70565 Stuttgart (Germany), with Notified Body ID number 0124.

PRODUCT*(S)* SUPPORTED BY THE ABOVE CERTIFICATE*(S)*

Product name:	***Pacific Xtreme***
Product description:	*PTA catheter*
Product codes:	*Refer to Annex I*
Device classification per MDD 93/42/EEC (Annex IX):	III

SIGNATURE *(on behalf of manufacturer)*:

Marco Brolis
Title: Regulatory Affairs Manager

PLACE AND DATE: Roncadelle, 19 FEB. 2019

Annex I: Pacific Xtreme product codes

PCF 020 020 090	PCF 025 150 180	PCF 035 150 130	PCF 045 080 090	PCF 055 030 180	PCF 065 020 180
PCF 020 020 130	PCF 030 020 090	PCF 035 150 180	PCF 045 080 130	PCF 055 040 090	PCF 065 030 090
PCF 020 020 180	PCF 030 020 130	PCF 040 020 090	PCF 045 080 180	**PCF 055 040 130**	PCF 065 030 130
PCF 020 030 090	**PCF 030 020 180**	**PCF 040 020 130**	PCF 045 120 090	PCF 055 040 180	PCF 065 030 180
PCF 020 030 130	PCF 030 030 090	PCF 040 020 180	PCF 045 120 130	PCF 055 060 090	PCF 065 040 090
PCF 020 030 180	PCF 030 030 130	PCF 040 030 090	PCF 045 120 180	PCF 055 060 130	PCF 065 040 130
PCF 020 040 090	PCF 030 030 180	PCF 040 030 130	PCF 045 150 090	PCF 055 060 180	PCF 065 040 180
PCF 020 040 130	PCF 030 040 090	PCF 040 030 180	PCF 045 150 130	PCF 055 080 090	PCF 065 060 090
PCF 020 040 180	PCF 030 040 130	PCF 040 040 090	PCF 045 150 180	PCF 055 080 130	PCF 065 060 130
PCF 020 060 090	PCF 030 040 180	PCF 040 040 130	PCF 050 020 090	PCF 055 080 180	PCF 065 060 180
PCF 020 060 130	PCF 030 060 090	PCF 040 040 180	PCF 050 020 130	PCF 055 120 090	PCF 065 080 090
PCF 020 060 180	PCF 030 060 130	PCF 040 060 090	PCF 050 020 180	PCF 055 120 130	PCF 065 080 130
PCF 020 080 090	PCF 030 060 180	PCF 040 060 130	PCF 050 030 090	PCF 055 120 180	PCF 065 080 180
PCF 020 080 130	PCF 030 080 090	PCF 040 060 180	PCF 050 030 130	PCF 060 020 090	PCF 065 120 090
PCF 020 080 180	PCF 030 080 130	PCF 040 080 090	PCF 050 030 180	PCF 060 020 130	PCF 065 120 130
PCF 020 120 090	PCF 030 080 180	PCF 040 080 130	PCF 050 040 090	PCF 060 020 180	PCF 065 120 180
PCF 020 120 130	PCF 030 120 090	PCF 040 080 180	PCF 050 040 130	PCF 060 030 090	PCF 070 020 090
PCF 020 120 180	PCF 030 120 130	PCF 040 120 090	PCF 050 040 180	PCF 060 030 130	PCF 070 020 130
PCF 020 150 090	PCF 030 120 180	PCF 040 120 130	PCF 050 060 090	PCF 060 030 180	PCF 070 020 180
PCF 020 150 130	PCF 030 150 090	PCF 040 120 180	PCF 050 060 130	PCF 060 040 090	PCF 070 030 090
PCF 020 150 180	PCF 030 150 130	PCF 040 150 090	PCF 050 060 180	PCF 060 040 130	PCF 070 030 130
PCF 025 020 090	PCF 030 150 180	PCF 040 150 130	PCF 050 080 090	PCF 060 040 180	PCF 070 030 180
PCF 025 020 130	PCF 035 020 090	PCF 040 150 180	PCF 050 080 130	**PCF 060 060 090**	PCF 070 040 090
PCF 025 020 180	PCF 035 020 130	PCF 040 200 090	PCF 050 080 180	PCF 060 060 130	PCF 070 040 130
PCF 025 030 090	PCF 035 020 180	PCF 040 200 130	PCF 050 120 090	PCF 060 060 180	PCF 070 040 180
PCF 025 030 130	PCF 035 030 090	PCF 040 250 090	PCF 050 120 130	PCF 060 080 090	PCF 070 060 090
PCF 025 030 180	PCF 035 030 130	PCF 040 250 130	PCF 050 120 180	PCF 060 080 130	PCF 070 060 130
PCF 025 040 090	PCF 035 030 180	PCF 040 300 090	PCF 050 150 090	PCF 060 080 180	PCF 070 060 180
PCF 025 040 130	PCF 035 040 090	PCF 040 300 130	PCF 050 150 130	PCF 060 120 090	PCF 070 080 090
PCF 025 040 180	PCF 035 040 130	PCF 045 020 090	PCF 050 150 180	PCF 060 120 130	PCF 070 080 130
PCF 025 060 090	PCF 035 040 180	PCF 045 020 130	PCF 050 200 090	PCF 060 120 180	PCF 070 080 180
PCF 025 060 130	PCF 035 060 090	PCF 045 020 180	PCF 050 200 130	PCF 060 150 090	PCF 070 120 090
PCF 025 060 180	PCF 035 060 130	PCF 045 030 090	PCF 050 250 090	PCF 060 150 130	PCF 070 120 130
PCF 025 080 090	PCF 035 060 180	PCF 045 030 130	PCF 050 250 130	PCF 060 200 090	PCF 070 120 180
PCF 025 080 130	PCF 035 080 090	PCF 045 030 180	PCF 050 300 090	PCF 060 200 130	PCF 070 150 090
PCF 025 080 180	PCF 035 080 130	PCF 045 040 090	PCF 050 300 130	PCF 060 250 090	**PCF 070 150 130**
PCF 025 120 090	PCF 035 080 180	PCF 045 040 130	PCF 055 020 090	PCF 060 250 130	PCF 070 200 090
PCF 025 120 130	PCF 035 120 090	PCF 045 040 180	PCF 055 020 130	PCF 060 300 090	PCF 070 200 130
PCF 025 120 180	PCF 035 120 130	PCF 045 060 090	PCF 055 020 180	PCF 060 300 130	PCF 070 250 090
PCF 025 150 090	PCF 035 120 180	PCF 045 060 130	PCF 055 030 090	PCF 065 020 090	PCF 070 250 130
PCF 025 150 130	PCF 035 150 090	PCF 045 060 180	PCF 055 030 130	PCF 065 020 130	

DECLARATION OF CONFORMITY

In according with EC Medical Device Directive 93/42/EEC (June 14, 1993)

We herewith declare that the below mentioned Medical Device is in conformity with the stated standards and the essential requirements of EC Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

Classification : Class III Rule 7 **Date CE550009 Affixed**: 11 Apr 2011
Date CE77043 Affixed: 12 Sep 2013

Conformity Assessment Route: Council Directive 93/42/EEC, Annex II,
Section 4 (CE550009)
Council Directive 93/42/EEC, Annex II,
Excluding Section 4 (CE77043)

Product Name : INTRAVASCULAR CATHETER WITH CUFF
Model Name : CELLO™ Balloon Guide Catheter

GMDN Code : 32584
UMDNS Code : 17846

Model No : 1610060, 1610070, 1610080, 1610090

Notified Body : British Standards Institution
NB No. : 0086
Address : Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP UK

Standards applied :

BS EN ISO 13485 (2012)	EN 62366 (2008)	ISO 15223 (2012)
BS EN 1041 (2008)	BS EN ISO 14971 (2012)	ISO 10993-1 (2009)
ISO 11135 (2014)	ISO 10993-7 (2008)	ISO 11607-1, 2 (2006)
ISO 594-1 (1986)	ISO 594-2 (1998)	ISO 10555-1 (2014)
ISO 10555-4 (2013)		

Authorized
Representative : Dr. Hans-Joachim Lau
Address : Airport Center (Building C) Flughafenstrasse 52a 22335 Hamburg Germany

Manufacturer : Fuji Systems Corporation Shirakawa Plant
Address : 200-2 Aza-Ohira, Odakura, Nishigo, Nishi Shirakawa Gun, Fukushima 961-8061 Japan

Fuji Systems Corporation
SIGN OFF:

DATE: 23. Apr. 2015

Shingo Ueki
Director, General Manager
Production Division

EC Certificate - Full Quality Assurance System

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

No. **CE 693494**

Issued To: **Covidien llc**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Design, Development and Manufacture of Sterile Percutaneous Transluminal Angioplasty (PTA) Catheters.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2018-07-18** Date: **2018-07-18** Expiry Date: **2020-12-16**

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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 693494**
Date:	**2018-07-18**
Issued To:	**Covidien llc** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Covidien llc 2300 Berkshire Lane North Plymouth Minnesota 55441 USA	**Design** **Development**
Covidien llc 3033 Campus Drive Plymouth Minnesota 55441 USA	**Regulatory Compliance**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	**ETO Sterilization**

...making excellence a habit.™

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 693494**
Date:	**2018-07-18**
Issued To:	**Covidien llc** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 693494**

Date: **2018-07-18**

Issued To: **Covidien llc**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Date	Reference Number	Action
Current	8939535	First issue. Transfer from another notified body.

Declaration of Conformity

Legal Manufacturer:	ev3, Inc. 4600 Nathan Lane North Plymouth, MN 55442 USA
EC Authorized Representative	Medtronic Ireland Parkmore Business Park West Galway Ireland
Design Facility:	Medtronic, Inc. (formerly d.b.a. ev3, Inc.) 2300 Berkshire Lane North Plymouth, MN 55441 USA
Manufacturing Facility:	ev3, Inc. 4600 Nathan Lane North Plymouth, MN 55442 USA
Product Family/ies:	Self-expanding peripheral stent system
Products:	EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System
Classification:	Class IIb based on Annex IX, Rule 8 of Directive 93/42/EEC (MDD)
Notified Body	BSI Group Kitemark Court, Davy Avenue Knowlhill, Milton Keynes, MK5 8PP Notified Body Number: 0086
Quality Management Systems Certificate	MD 660553
EC Certificate- Full Quality Assurance	CE 684995

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), including amendments issued, which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by the MDD, Annex II.3 Approval.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Plymouth, Minnesota, USA Date: 04 JAN 2018

Name: David Worrell

Title Sr. Regulatory Affairs Director Signature

Products: EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System

Model Numbers		
EVX35-05-020-080	**EVX35-06-060-120**	EVX35-07-100-150
EVX35-05-020-120	EVX35-06-060-150	EVX35-07-120-080
EVX35-05-020-150	EVX35-06-080-080	EVX35-07-120-120
EVX35-05-040-080	EVX35-06-080-120	EVX35-07-120-150
EVX35-05-040-120	EVX35-06-080-150	EVX35-07-150-080
EVX35-05-040-150	EVX35-06-100-080	EVX35-07-150-120
EVX35-05-060-080	EVX35-06-100-120	EVX35-07-150-150
EVX35-05-060-120	EVX35-06-100-150	EVX35-08-020-080
EVX35-05-060-150	EVX35-06-120-080	EVX35-08-020-120
EVX35-05-080-080	EVX35-06-120-120	EVX35-08-020-150
EVX35-05-080-120	EVX35-06-120-150	EVX35-08-040-080
EVX35-05-080-150	EVX35-06-150-080	EVX35-08-040-120
EVX35-05-100-080	EVX35-06-150-120	EVX35-08-040-150
EVX35-05-100-120	EVX35-06-150-150	EVX35-08-060-080
EVX35-05-100-150	EVX35-07-020-080	EVX35-08-060-120
EVX35-05-120-080	EVX35-07-020-120	EVX35-08-060-150
EVX35-05-120-120	EVX35-07-020-150	EVX35-08-080-080
EVX35-05-120-150	EVX35-07-040-080	EVX35-08-080-120
EVX35-05-150-080	EVX35-07-040-120	EVX35-08-080-150
EVX35-05-150-120	EVX35-07-040-150	EVX35-08-100-080
EVX35-05-150-150	EVX35-07-060-080	EVX35-08-100-120
EVX35-06-020-080	EVX35-07-060-120	EVX35-08-100-150
EVX35-06-020-120	EVX35-07-060-150	EVX35-08-120-080
EVX35-06-020-150	EVX35-07-080-080	EVX35-08-120-120
EVX35-06-040-080	EVX35-07-080-120	EVX35-08-120-150
EVX35-06-040-120	EVX35-07-080-150	EVX35-08-150-080
EVX35-06-040-150	EVX35-07-100-080	EVX35-08-150-120
EVX35-06-060-080	EVX35-07-100-120	EVX35-08-150-150

Revision History

Revision	Date	Description of Change
F	04-JAN-2018	Update to new template, change notified body to BSI, update EU authorized rep, update EC quality certificate

Declaration of Conformity

Legal Manufacturer:	Covidien llc 4600 Nathan Lane North Plymouth, MN 55442 USA
EC Authorized Representative	Medtronic Ireland Parkmore Business Park West Galway Ireland
Design Facility:	Medtronic, Inc. (formerly d.b.a. Covidien llc) 2300 Berkshire Lane North Plymouth, MN 55441 USA
Manufacturing Facility:	Covidien llc 4600 Nathan Lane North Plymouth, MN 55442 USA
Product Family/ies:	PTA Balloon Catheters
Products:	Fortrex™ 0.035" OTW PTA Balloon Catheter
Classification:	Class IIa based on Annex IX, Rule 6 of Directive 93/42/EEC (MDD)
Notified Body	BSI Group Kitemark Court, Davy Avenue Knowlhill, Milton Keynes, MK5 8PP Notified Body Number: 0086
Quality Management Systems Certificate	MD 660552
EC Certificate- Full Quality Assurance	CE 693494
EC Design Certificate	Not applicable

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), including amendments issued, which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by the MDD, Annex II.3 Approval.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Plymouth, Minnesota, USA Date: Aug. 2, 2018

Name: Monika McDole-Russell

Title Regulatory Affairs Manager Signature Monika McDole-Russell

Products:

Product	Fortrex™ 0.035" OTW PTA Balloon Catheter	
Class-Rule	Class IIa, Annex IX, Rule 6	
Date CE Mark Affixed	December 12, 2014	
Product Codes		
A35HPV08040040	A35HPV09040040	A35HPV10080080
A35HPV08080040	A35HPV10040040	A35HPV12040080

Product	Fortrex™ 0.035" OTW PTA Balloon Catheter	
Class-Rule	Class IIa, Annex IX, Rule 6	
Date CE Mark Affixed	February 02, 2015	
Product Codes		
A35HPV04040080	A35HPV04040135	A35HPV05040040
A35HPV05040080	A35HPV05040135	A35HPV06040040
A35HPV06040080	A35HPV07040040	A35HPV07040080
A35HPV08040080	A35HPV08080080	A35HPV09040080
A35HPV10040080		

Product	Fortrex™ 0.035" OTW PTA Balloon Catheter	
Class-Rule	Class IIa, Annex IX, Rule 6	
Date CE Mark Affixed	April 27, 2015	
Product Codes		
A35HPV04020040	A35HPV04020080	A35HPV04020135
A35HPV04040040	A35HPV04080040	A35HPV04080080
A35HPV04080135	A35HPV04100040	A35HPV04100080
A35HPV04100135	A35HPV05020040	A35HPV05020080
A35HPV05020135	A35HPV05080040	A35HPV05080080
A35HPV05080135	A35HPV05100040	A35HPV05100080
A35HPV05100135	A35HPV06020040	A35HPV06020080
A35HPV06020135	A35HPV06040135	A35HPV06080040
A35HPV06080080	A35HPV06080135	A35HPV06100040
A35HPV06100080	A35HPV06100135	A35HPV07020040
A35HPV07020080	A35HPV07020135	A35HPV07040135
A35HPV07080040	A35HPV07080080	A35HPV07080135
A35HPV07100040	A35HPV07100080	A35HPV07100135
A35HPV08040135	A35HPV08080135	A35HPV08100040
A35HPV08100080	A35HPV08100135	A35HPV09040135
A35HPV09080040	A35HPV09080080	A35HPV09080135
A35HPV10040135	A35HPV10080040	A35HPV10080135
A35HPV12040040	A35HPV12040135	A35HPV12080040
A35HPV12080080	A35HPV12080135	

Revision History

Revision	Date	Description of Change
F	02 Aug-2018	Update to new template, change notified body to BSI, update EU authorized rep, update ISO 13485 and EC quality certificate.

EC Certificate - Full Quality Assurance System

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

No. **CE 84868**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

In respect of:

The design, development and manufacture of sterile Endoluminal Stent Grafts, sterile Securement Devices and Delivery Systems for Endovascular Indications, sterile Vascular Introducer Sheaths, sterile Stent Graft Balloon Catheters, sterile Iliac Stents and Delivery Systems, sterile Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems, sterile Coronary Stents and Delivery Systems, Sterile Intravascular Catheters and sterile/non-sterile Catheter Systems for Renal Denervation.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2004-08-24** Date: **2018-05-01** Expiry Date: **2019-08-23**

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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 84868**
Date:	**2018-05-01**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Admedes Scheuessler GmbH Rastatter Str. 15 75179 Pforzheim Germany	**Manufacture**
Flextronics International GmbH Niederlassung Althofen Friesacher Strasse 3 9330 Althofen Austria	**Manufacture**
INVATEC S.p.A Via Martiri della Libertà 7 Roncadelle (BS) 25030 Italy	**Manufacture**
Medistri SA Rte de I'Industrie 96 Case Postale 115 1564 Domdidier Switzerland	**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 84868**
Date:	**2018-05-01**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	**EU Representative**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**Design** **EU Representative** **Manufacture**
Medtronic Mexico EG Carret. Int. Km. 1969 Guad.-Nogales Km.2 Empalme, Sonora 85340 Mexico	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**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 84868**
Date:	**2018-05-01**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Vascular 3576 Unocal Place Santa Rosa CA 95403 USA	**Design**
Plexus Corp. Pinnacle Hill Kelso TD5 8XX United Kingdom	**Manufacture**
Plexus Manufacturing SDN BHD Bayan Lepas Free Industrial Zone Phase II, 11900 Bayan Lepas Penang Malaysia	**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 84868**
Date:	**2018-05-01**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
SSP-SiMatrix 1131 North US Hwy 93 Victor Montana 59875 USA	**Manufacture**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	**E Beam Sterilization** **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 84868**
Date:	**2018-05-01**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Ind. Estate Daventry Northamptonshire NN11 8RB United Kingdom	**E Beam Sterilization**
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	**Gamma Sterilization**
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **2018-05-01**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
24 August 2004		First Issued.
15 November 2004		Transfer of the following certificates from NSAI:- Q252.322, Q252.407, Q252.426, Q252.427, Q252.428, Q252.467, Q252.480, Q252.587, and Q252.611 D252.587 and D252.407, plus incorporation of Medtronic Vascular Ireland as a subcontract manufacturer.
02 December 2004		Carotid and Coronary Stents and Delivery Systems added to the scope (transfer) Medtronic Mexico (manufacture), and Titan Scan Systems, Nutec Corporation, Sterigenics (Queensbury), Steris Corporation-Isomedix Services (Sandy), Rocialle in Health (Mid Glamorgan UK), and EBIS Iotron added as sub-contract sterilizers.
21 December 2004		PCTA Balloon Dilatation Catheters added to the range of products manufactured (transferred from another Notified Body) and Isotron Ireland Ltd added as sub-contract sterilization site.
19 August 2005		Sterilization sub-contractor name change from Titan Scan Systems to Beam One.
03 April 2006		Addition of Sterigenics UK Ltd, as sterilization sub-contractor.
07 August 2006		Addition of AD)MEDES Schuessler GmbH as a sub-contractor for manufacture.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **2018-05-01**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
11 January 2008	7149866	Subcontractor name change from EBIS Isotron, Harwell to Isotron Harwell. Addition of Isotron plc, Daventry as a subcontractor for E beam sterilization.
03 October 2008	7279045	Addition of Medtronic Mexico EG, Empalme as a subcontractor for manufacture.
14 April 2009	7341499	Correction of the legal name of the Medtronic Mexico facility and postcode for the Isotron PLC, Daventry facility. Addition of the activity of EU Representative for Medtronic Ireland.
13 August 2009	7432878	Certificate renewal. Addition of Accellant Inc as a manufacturing subcontractor, amendment to company name for Isotron PLC, Daventry, and Steris Corporation, Sandy, Utah. Change to address for the subcontractor, Nutek Corporation. Addition of E Beam Sterilization for Isotron Ireland. Rewording of scope for clarification purposes only.
29 July 2010	7546410	Added C.R. Bard, Inc. to the list of significant subcontractors for manufacturing. Extended the scope to include guidewires.
12 October 2011	7730209	Extension to scope to include Catheter Systems for Renal Denervation. Removal of Carotid Stents and Delivery Systems from the scope. Minor amendments to Isotron Daventry and Isotron Tullamore's addresses.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **2018-05-01**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
26 January 2012	7792125	Amendment to significant subcontractors to reflect Isotron's name change to Synergy Health and removal of Isotron Harwell.
25 May 2012	7842435	Amendment to the address format and zip code for the significant subcontractor Medtronic Mexico (Tijuana).
19 December 2012	7915649	Addition of Medtronic B.V. The Netherlands for EU Representative Activities.
22 January 2013	7945194	Extension to scope to include Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems.
28 February 2013	7960715	Addition of Invatec Technology Center GmbH to the list of significant subcontractors for manufacturing activities.
28 March 2013	7943883	Extension to Scope to include Vascular Introducer Sheaths and the addition of Teleflex Medical for manufacturing activities.
16 December 2013	8082854	Addition of Plexus Manufacturing Sdn Bhd, Malaysia and Plexus Corp, UK to the list of significant subcontractors for manufacturing activities.
13 July 2014	8154862	Certificate Renewal. Various updates and changes to the list of significant subcontractors. Correction of the reference number for the reissue dated 19th December 2012 on the certificate history page.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **2018-05-01**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
31 July 2015	8350802	Addition of SSP SiMATrix Inc. as balloon supplier for the Attain Clarity.
01 July 2016	8545838	C. R. Bard, Inc., Medtronic Ardian LLC, Nutek Corporation, Sterigenics NY and Apical Instruments Inc. were removed from the list of significant subcontractors.
09 October 2017	8696759	Certificate scope updated to add the design, development and manufacture of securement devices for endovascular indications.
Current	8895951	Specify devices covered in this certificate are sterile/non-sterile. Move 'sterile Vascular Introducer Sheaths' up in the scope after securement devices. Remove 'Renal Stents and Delivery Systems' and 'guidewires for diagnostic or interventional procedures' from scope. Correction to certificate history entry #2 from '2014' to '2004'.

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Invatec S.p.A.

Via Martiri della Libertà 7, 25030 Roncadelle (BS), Italy

Certified location:

Via Martiri della Libertà 7, 25030 Roncadelle (BS), Italy

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50251-Z6-00, the decision dated 2019-02-09 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-02-16 to 2024-02-15

Registration No.: 50251-16-09

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-02-09
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50251-16-09

Valid from 2019-02-16 to 2024-02-15

Revision status of the annex: 0 dated 2019-02-16

Devices/device categories included in the certificate:

Class II a:

- PTA catheter
  - Amphirion Deep
  - Admiral Xtreme

Class II b:

- Renal stent system
  - Hippocampus

Class III:

- PTA catheter
  - Submarine Rapido
  - Pacific Xtreme
- Carotid guide catheter
  - PITON GC
- Cerebral protection device
  - MO.MA ULTRA

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-02-09
Notified Body ID-number: 0124

Declaration of Conformity

IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)

Legal Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Authorized Representative	Medtronic Ireland Parkmore Business Park West Galway, Ireland
Design Facility:	Medtronic Vascular 3576 Unocal Place Santa Rosa, CA 95403 USA
Manufacturing Facility:	Medtronic Ireland Parkmore Business Park West Galway, Ireland
Product Family/ies:	Paclitaxel-coated PTA Balloon Catheter
Products:	IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter) [Formerly IN.PACT Admiral (Paclitaxel-eluting PTA Balloon Catheter)] Refer to page 3 for Model No.
Classification:	Class III based on Annex IX, Rule 13 of Directive 93/42/EEC (MDD)

Notified Body	BSI, Notified Body Number 0086
EC Quality Certificate	CE 84868 issued on 24 August 2004
EC Design Certificate	CE 570280 issued on 12 December 2018

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), including amendments issued, which apply to them, as transposed into the national laws of the EU member states

This declaration is supported by the MDD, Annex II.3 Approval as well as the EC Design Examination Certificate listed above.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Medtronic Vascular, Inc. Santa Rosa, CA (USA) Date: Dec 13th 2018

Name: Áine Smalley

Title Vice President Regulatory Affairs Signature Áine Smalley

Products: IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)

Model Name	Model No.
IN.PACT Admiral	SBI 040 020 04P
IN.PACT Admiral	SBI 040 040 04P
IN.PACT Admiral	SBI 040 060 04P
IN.PACT Admiral	SBI 040 080 04P
IN.PACT Admiral	SBI 040 120 04P
IN.PACT Admiral	SBI 040 150 04P
IN.PACT Admiral	SBI 050 020 04P
IN.PACT Admiral	SBI 050 040 04P
IN.PACT Admiral	SBI 050 060 04P
IN.PACT Admiral	SBI 050 080 04P
IN.PACT Admiral	SBI 050 120 04P
IN.PACT Admiral	SBI 050 150 04P
IN.PACT Admiral	SBI 060 020 04P
IN.PACT Admiral	SBI 060 040 04P
IN.PACT Admiral	SBI 060 060 04P
IN.PACT Admiral	SBI 060 080 04P
IN.PACT Admiral	SBI 060 120 04P
IN.PACT Admiral	SBI 060 150 04P
IN.PACT Admiral	SBI 070 020 04P
IN.PACT Admiral	SBI 070 040 04P
IN.PACT Admiral	SBI 070 060 04P
IN.PACT Admiral	SBI 070 080 04P
IN.PACT Admiral	SBI 080 040 04P
IN.PACT Admiral	SBI 080 060 04P
IN.PACT Admiral	SBI 080 080 04P
IN.PACT Admiral	SBI 090 040 04P
IN.PACT Admiral	SBI 090 060 04P
IN.PACT Admiral	SBI 090 080 04P
IN.PACT Admiral	SBI 100 040 04P
IN.PACT Admiral	SBI 120 040 04P
IN.PACT Admiral	SBI 040 020 08P
IN.PACT Admiral	SBI 040 040 08P
IN.PACT Admiral	SBI 040 060 08P
IN.PACT Admiral	SBI 040 080 08P
IN.PACT Admiral	SBI 040 120 08P
IN.PACT Admiral	SBI 040 150 08P
IN.PACT Admiral	SBI 040 200 08P
IN.PACT Admiral	SBI 040 250 08P
IN.PACT Admiral	SBI 050 020 08P
IN.PACT Admiral	SBI 050 040 08P
IN.PACT Admiral	SBI 050 060 08P
IN.PACT Admiral	SBI 050 080 08P

Model Name	Model No.
IN.PACT Admiral	SBI 050 120 08P
IN.PACT Admiral	SBI 050 150 08P
IN.PACT Admiral	SBI 050 200 08P
IN.PACT Admiral	SBI 050 250 08P
IN.PACT Admiral	SBI 060 020 08P
IN.PACT Admiral	SBI 060 040 08P
IN.PACT Admiral	SBI 060 060 08P
IN.PACT Admiral	SBI 060 080 08P
IN.PACT Admiral	SBI 060 120 08P
IN.PACT Admiral	SBI 060 150 08P
IN.PACT Admiral	SBI 060 200 08P
IN.PACT Admiral	SBI 060 250 08P
IN.PACT Admiral	SBI 070 020 08P
IN.PACT Admiral	SBI 070 040 08P
IN.PACT Admiral	SBI 070 060 08P
IN.PACT Admiral	SBI 070 080 08P
IN.PACT Admiral	SBI 080 040 08P
IN.PACT Admiral	SBI 080 060 08P
IN.PACT Admiral	SBI 080 080 08P
IN.PACT Admiral	SBI 090 040 08P
IN.PACT Admiral	SBI 090 060 08P
IN.PACT Admiral	SBI 090 080 08P
IN.PACT Admiral	SBI 100 040 08P
IN.PACT Admiral	SBI 120 040 08P
IN.PACT Admiral	SBI 040 020 13P
IN.PACT Admiral	SBI 040 040 13P
IN.PACT Admiral	SBI 040 060 13P
IN.PACT Admiral	SBI 040 080 13P
IN.PACT Admiral	SBI 040 120 13P
IN.PACT Admiral	SBI 040 150 13P
IN.PACT Admiral	SBI 040 200 13P
IN.PACT Admiral	SBI 040 250 13P
IN.PACT Admiral	SBI 050 020 13P
IN.PACT Admiral	SBI 050 040 13P
IN.PACT Admiral	SBI 050 060 13P
IN.PACT Admiral	SBI 050 080 13P
IN.PACT Admiral	SBI 050 120 13P
IN.PACT Admiral	SBI 050 150 13P
IN.PACT Admiral	SBI 050 200 13P
IN.PACT Admiral	SBI 050 250 13P
IN.PACT Admiral	SBI 060 020 13P
IN.PACT Admiral	SBI 060 040 13P

Model Name	Model No.
IN.PACT Admiral	SBI 060 060 13P
IN.PACT Admiral	SBI 060 080 13P
IN.PACT Admiral	SBI 060 120 13P
IN.PACT Admiral	SBI 060 150 13P
IN.PACT Admiral	SBI 060 200 13P
IN.PACT Admiral	SBI 060 250 13P
IN.PACT Admiral	SBI 070 020 13P
IN.PACT Admiral	SBI 070 040 13P
IN.PACT Admiral	SBI 070 060 13P

Model Name	Model No.
IN.PACT Admiral	SBI 070 080 13P
IN.PACT Admiral	SBI 080 040 13P
IN.PACT Admiral	SBI 080 060 13P
IN.PACT Admiral	SBI 080 080 13P
IN.PACT Admiral	SBI 090 040 13P
IN.PACT Admiral	SBI 090 060 13P
IN.PACT Admiral	SBI 090 080 13P
IN.PACT Admiral	SBI 100 040 13P
IN.PACT Admiral	SBI 120 040 13P

Revision History

Revision	Date	Description of Change
1A	08/08/2014	First Issue: Legal manufacturer transferred to Medtronic, Inc., manufacturing of finished device and Authorized Representative transferred to Medtronic Ireland
1B	09/01/2015	Expand the indication for use to include the treatment of in-stent restenosis (ISR)
1C	18/09/2015	Coating process and inspection changes
1D	08/10/2015	Dupont Tyvek change
1E	05/01/2016	Addition of building 2, Medtronic Ireland, for the manufacture of IN.PACT Admiral devices. Line extension to include 8 new balloon sizes for the 40cm long catheters. Expand the indication for use to include the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae
1F	18/10/2016	Introduction of the in-line degasser to the Hamilton Pump used to coat IN.PACT Admiral device
1G	21/02/2017	Line extension to include balloons with 8-12mm diameters. Removal of stylet from all sizes. Renamed as "IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)"
1H	DD/MM/YYYY	Line extension to include balloons with 200-250mm lengths
1 J	12/12/2018	Recertification

EC Design-Examination Certificate

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

No. **CE 570280**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

In respect of:

IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)
[Formerly IN.PACT Admiral (Paclitaxel-eluting PTA Balloon Catheter)]

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2011-03-15** Date: **2018-12-12** Expiry Date: **2023-12-19**

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EC Design-Examination Certificate

Supplementary Information to CE 570280

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product: IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)
[Formerly IN.PACT Admiral (Paclitaxel-eluting PTA Balloon Catheter)]

Technical specifications

Catheter usable length (cm)	40	80	130
Balloon diameter (mm)	4.0 / 5.0 / 6.0 / 7.0/ 8.0 / 9.0 / 10.0 / 12.0	4.0 / 5.0 / 6.0 / 7.0/ 8.0 / 9.0 / 10.0 / 12.0	4.0 / 5.0 / 6.0 / 7.0/ 8.0 / 9.0 / 10.0 / 12.0
Balloon length (mm)	20 / 40 / 60 / 80 / 120 / 150	20 / 40 / 60 / 80 / 120 / 150	20 / 40 / 60 / 80 / 120 / 150
Construction type	OTW	OTW	OTW
Number of markers	2	2	2

Product Codes

The product family is composed by the following group of products:

Product code: AAA XXX YYY KKZ :

AAA: Family name SBI (IN.PACT Admiral)

XXX: Nominal balloon diameter (4.0mm=040 … 12.0mm=120)

YYY: Nominal balloon length (20mm=020 … 150mm=150)

KK: Catheter usable length (40mm=04; 80mm=08; 130mm=13)

Z: P = DCB, Drug Coated Balloon

First Issued: **2011-03-15** Date: **2018-12-12** Expiry Date: **2023-12-19**

EC Design-Examination Certificate

Supplementary Information to CE 570280

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

IN.PACT Admiral product code		
Usable length 40 cm	**Usable length 80 cm**	**Usable length 130 cm**
SBI 040 020 04P	SBI 040 020 08P	SBI 040 020 13P
SBI 040 040 04P	SBI 040 040 08P	SBI 040 040 13P
SBI 040 060 04P	SBI 040 060 08P	SBI 040 060 13P
SBI 040 080 04P	SBI 040 080 08P	SBI 040 080 13P
SBI 040 120 04P	SBI 040 120 08P	SBI 040 120 13P
SBI 040 150 04P	SBI 040 150 08P	SBI 040 150 13P
SBI 050 020 04P	SBI 050 020 08P	SBI 050 020 13P
SBI 050 040 04P	SBI 050 040 08P	SBI 050 040 13P
SBI 050 060 04P	SBI 050 060 08P	SBI 050 060 13P
SBI 050 080 04P	SBI 050 080 08P	SBI 050 080 13P
SBI 050 120 04P	SBI 050 120 08P	SBI 050 120 13P
SBI 050 150 04P	SBI 050 150 08P	SBI 050 150 13P
SBI 060 020 04P	SBI 060 020 08P	SBI 060 020 13P
SBI 060 040 04P	SBI 060 040 08P	SBI 060 040 13P
SBI 060 060 04P	SBI 060 060 08P	SBI 060 060 13P
SBI 060 080 04P	SBI 060 080 08P	SBI 060 080 13P
SBI 060 120 04P	SBI 060 120 08P	SBI 060 120 13P
SBI 060 150 04P	SBI 060 150 08P	SBI 060 150 13P
SBI 070 020 04P	SBI 070 020 08P	SBI 070 020 13P
SBI 070 040 04P	SBI 070 040 08P	SBI 070 040 13P
SBI 070 060 04P	SBI 070 060 08P	SBI 070 060 13P
SBI 070 080 04P	SBI 070 080 08P	SBI 070 080 13P

First Issued: **2011-03-15** Date: **2018-12-12** Expiry Date: **2023-12-19**

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EC Design-Examination Certificate

Supplementary Information to CE 570280

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Usable length 40 cm	Usable length 80 cm	Usable length 130 cm
SBI 080 040 04P	SBI 080 040 08P	SBI 080 040 13P
SBI 080 060 04P	SBI 080 060 08P	SBI 080 060 13P
SBI 080 080 04P	SBI 080 080 08P	SBI 080 080 13P
SBI 090 040 04P	SBI 090 040 08P	SBI 090 040 13P
SBI 090 060 04P	SBI 090 060 08P	SBI 090 060 13P
SBI 090 080 04P	SBI 090 080 08P	SBI 090 080 13P
SBI 100 040 04P	SBI 100 040 08P	SBI 100 040 13P
SBI 120 040 04P	SBI 120 040 08P	SBI 120 040 13P

First Issued: **2011-03-15** Date: **2018-12-12** Expiry Date: **2023-12-19**

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EC Design-Examination Certificate

Supplementary Information to CE 570280

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Certificate History

Date	Reference Number	Action
15 March 2011	10119529	First Issue – Transfer from another Notified Body
22 February 2012	10131424	Modified lot release tests
10 October 2012	10137174	Modified manufacturing processes and lot release tests
12 September 2013	10141429	Line extension to include 150mm balloons. Shelf life extended to 3 years.
10 October 2013	10143954	Certificate renewal
08 August 2014	10147237	INVATEC Technology Center GmbH replaced by Medtronic, Inc. as legal manufacturer. Manufacturing activities moved to Medtronic Ireland. Addition of Medtronic Mexico S. de R.L. de CV for manufacturing activities.
09 January 2015	10146522	Indication extended to include the treatment of in-stent restenosis.
17 September 2015	10156875	Coating process and inspection changes.
06 October 2015	10157079	Dupont Tyvek Change.

First Issued: **2011-03-15** Date: **2018-12-12** Expiry Date: **2023-12-19**

EC Design-Examination Certificate

Supplementary Information to CE 570280

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Certificate History

Date	Reference Number	Action
04 January 2016	10154843	Line extension to include 8 new balloon sizes for the 40cm long catheters. Indication extended to include treatment of obstructive lesions of native or synthetic arteriovenous fistulae.
04 January 2016	10159826	Addition of building 2, Medtronic Ireland, for the Manufacture of IN.PACT Admiral device, Corrected typo in history section: EQ 10158675 replaced by EQ 10156875.
17 October 2016	10164679	Introduction of an in-line degasser to the Hamilton Pump used to coat the IN.PACT Admiral device.
21 February 2017	10166722	Line extension to include balloons with 8-12mm diameters. Removal of stylet from all sizes. Renamed as "IN.PACT Admiral (Paclitaxel-coated PTA balloon catheter)".
Current	9630066	Certificate renewal.

First Issued: **2011-03-15** Date: **2018-12-12** Expiry Date: **2023-12-19**

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Declaration of Conformity

IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)

Legal Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Authorized Representative	Medtronic Ireland Parkmore Business Park West Galway, Ireland
Design Facility:	Medtronic Vascular 3576 Unocal Place Santa Rosa, CA 95403 USA
Manufacturing Facility:	Medtronic Ireland Parkmore Business Park West Galway, Ireland
Product Family/ies:	Paclitaxel-eluting PTA Balloon Catheter
Products:	IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter) (Refer to page 3 for model no.)
Classification:	Class III based on Annex IX, Rule 13 of Directive 93/42/EEC (MDD)
Notified Body	BSI, Notified Body Number 0086
EC Quality Certificate	CE 84868 issued on 24 August 2004
EC Design Certificate	CE 570281 issued on 11 December 2018

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), including amendments issued, which apply to them, as transposed into the national laws of the EU member states

This declaration is supported by the MDD, Annex II.3 Approval as well as the EC Design Examination Certificate listed above.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Medtronic Vascular, Inc.
Santa Rosa, CA (USA)

Date: Dec 13th 2018

Name: Áine Smalley

Title Vice President Regulatory Affairs

Signature Áine Smalley

Products: IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)

Model Name	Model No.	Model Name	Model No.
IN.PACT Pacific	PCF 040 040 09P	IN.PACT Pacific	PCF 060 040 13P
IN.PACT Pacific	PCF 040 060 09P	IN.PACT Pacific	PCF 060 060 13P
IN.PACT Pacific	PCF 040 080 09P	IN.PACT Pacific	PCF 060 080 13P
IN.PACT Pacific	PCF 040 120 09P	IN.PACT Pacific	PCF 060 120 13P
IN.PACT Pacific	PCF 050 040 09P	IN.PACT Pacific	PCF 070 040 13P
IN.PACT Pacific	PCF 050 060 09P	IN.PACT Pacific	PCF 070 060 13P
IN.PACT Pacific	PCF 050 080 09P	IN.PACT Pacific	PCF 070 080 13P
IN.PACT Pacific	PCF 050 120 09P	IN.PACT Pacific	PCF 070 120 13P
IN.PACT Pacific	PCF 060 040 09P	IN.PACT Pacific	PCF 040 040 18P
IN.PACT Pacific	PCF 060 060 09P	IN.PACT Pacific	PCF 040 060 18P
IN.PACT Pacific	PCF 060 080 09P	IN.PACT Pacific	PCF 040 080 18P
IN.PACT Pacific	PCF 060 120 09P	IN.PACT Pacific	PCF 040 120 18P
IN.PACT Pacific	PCF 070 040 09P	IN.PACT Pacific	PCF 050 040 18P
IN.PACT Pacific	PCF 070 060 09P	IN.PACT Pacific	PCF 050 060 18P
IN.PACT Pacific	PCF 070 080 09P	IN.PACT Pacific	PCF 050 080 18P
IN.PACT Pacific	PCF 070 120 09P	IN.PACT Pacific	PCF 050 120 18P
IN.PACT Pacific	PCF 040 040 13P	IN.PACT Pacific	PCF 060 040 18P
IN.PACT Pacific	PCF 040 060 13P	IN.PACT Pacific	PCF 060 060 18P
IN.PACT Pacific	PCF 040 080 13P	IN.PACT Pacific	PCF 060 080 18P
IN.PACT Pacific	PCF 040 120 13P	IN.PACT Pacific	PCF 060 120 18P
IN.PACT Pacific	PCF 050 040 13P	IN.PACT Pacific	PCF 070 040 18P
IN.PACT Pacific	PCF 050 060 13P	IN.PACT Pacific	PCF 070 060 18P
IN.PACT Pacific	PCF 050 080 13P	IN.PACT Pacific	PCF 070 080 18P
IN.PACT Pacific	PCF 050 120 13P	IN.PACT Pacific	PCF 070 120 18P

Revision History

Revision	Date	Description of Change
1A	08/08/2014	First Issue: Legal manufacturer transferred to Medtronic, Inc., manufacturing of finished device and Authorized Representative transferred to Medtronic Ireland
1B	18/09/2015	Coating process and inspection changes
1C	08/10/2015	Dupont Tyvek change.
1D	26/01/2016	Add Building 2 at Medtronic Ireland as manufacturing location
1E	18/10/2016	Introduction of the in-line degasser to the Hamilton Pump used to coat IN.PACT Pacific device
1F	11/12/2018	Recertification

EC Design-Examination Certificate

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

No. **CE 570281**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

In respect of:

IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2011-03-15** Date: **2018-12-11** Expiry Date: **2023-12-19**

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EC Design-Examination Certificate

Supplementary Information to CE 570281

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product: IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)

Technical specifications

Catheter usable length (cm)	90	130	180
Balloon diameter (mm)	4.0 / 5.0 / 6.0 / 7.0	4.0 / 5.0 / 6.0 / 7.0	4.0 / 5.0 / 6.0 / 7.0
Balloon length (mm)	40 / 60 / 80 / 120	40 / 60 / 80 / 120	40 / 60 / 80 / 120
Construction type	OTW	OTW	OTW
Number of markers	2	2	2

Product Codes

The product family is composed by the following group of products:

Product code: AAA XXX YYY KKZ

AAA: Family name PCF (IN.PACT Pacific)

XXX: Nominal balloon diameter (4.0mm=040 … 7.0mm=070)

YYY: Nominal balloon length (40mm=040 … 120mm=120)

KK: Catheter usable length (90cm=09; 130cm=13; 180cm=18)

Z: P = DEB, Drug Eluting Balloon

First Issued: **2011-03-15** Date: **2018-12-11** Expiry Date: **2023-12-19**

EC Design-Examination Certificate

Supplementary Information to CE 570281

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

IN.PACT Pacific product code		
Usable length 90 cm	**Usable length 130 cm**	**Usable length 180 cm**
PCF 040 040 09P	PCF 040 040 13P	PCF 040 040 18P
PCF 040 060 09P	PCF 040 060 13P	PCF 040 060 18P
PCF 040 080 09P	PCF 040 080 13P	PCF 040 080 18P
PCF 040 120 09P	PCF 040 120 13P	PCF 040 120 18P
PCF 050 040 09P	PCF 050 040 13P	PCF 050 040 18P
PCF 050 060 09P	PCF 050 060 13P	PCF 050 060 18P
PCF 050 080 09P	PCF 050 080 13P	PCF 050 080 18P
PCF 050 120 09P	PCF 050 120 13P	PCF 050 120 18P
PCF 060 040 09P	PCF 060 040 13P	PCF 060 040 18P
PCF 060 060 09P	PCF 060 060 13P	PCF 060 060 18P
PCF 060 080 09P	PCF 060 080 13P	PCF 060 080 18P
PCF 060 120 09P	PCF 060 120 13P	PCF 060 120 18P
PCF 070 040 09P	PCF 070 040 13P	PCF 070 040 18P
PCF 070 060 09P	PCF 070 060 13P	PCF 070 060 18P
PCF 070 080 09P	PCF 070 080 13P	PCF 070 080 18P
PCF 070 120 09P	PCF 070 120 13P	PCF 070 120 18P

First Issued: **2011-03-15** Date: **2018-12-11** Expiry Date: **2023-12-19**

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EC Design-Examination Certificate

Supplementary Information to CE 570281

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Certificate History

Date	Reference Number	Action
15 March 2011	10119530	First Issue – Transfer from another Notified Body
22 February 2012	10131424	Modified paclitaxel coating process and lot release tests
25 October 2013	10143958	Certificate renewal
08 August 2014	10149873	INVATEC Technology Center GmbH replaced by Medtronic, Inc. as legal manufacturer. Manufacturing activities moved to Medtronic Ireland. Addition of Medtronic Mexico S. de R.L. de CV for manufacturing activities.
17 September 2015	10156875	Coating process and inspection changes.
06 October 2015	10157079	Dupont Tyvek Change
04 January 2016	10159826	Addition of building 2, Medtronic Ireland, for the manufacture of the IN.PACT Pacific device. Corrected typo in history section: EQ 10158675 replaced by EQ 10156875.
17 October 2016	10164679	Introduction of an in-line degasser to the Hamilton Pump used to coat the IN.PACT Pacific device.
Current	9640965	Certificate renewal.

First Issued: **2011-03-15** Date: **2018-12-11** Expiry Date: **2023-12-19**

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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, occlusion balloon catheters, micro catheters, guide 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 and neurovascular revascularization devices.

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	170723947
Effective date	2018-11-22
Expiry date	2020-11-30
Frankfurt am Main	2018-11-22

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

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

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 281863 MP2016
Certificate unique ID: 170723947
Effective date: 2018-11-22

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

Location	Scope
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, occlusion balloon catheters, micro catheters, guide 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 and neurovascular revascularization devices.
Micro Therapeutics, Inc. **DBA ev3 Neurovascular** 9 Parker Irvine, CA, 92618 United States of America	Design and development of infusion catheters, valved infusion catheters, infusion wires, hydrophilic stainless steel guidewires, occlusion balloon catheters, micro catheters, guide 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 and neurovascular revascularization devices.
Micro Therapeutics, Inc. **DBA ev3 Neurovascular** 6 Cromwell Irvine, CA, 92618 United States of America	Administration and warehouse for engineering materials, equipment, components and raw materials.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

ev3, Inc.
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Holds Certificate Number: MD 660553

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design and manufacture of sterile medical devices: Guidewires; Snares, Microsnares, Snare Catheters and Microcatheters; Endovascular Catheters; Rotating Y-Connectors; Thrombectomy Devices; Atherectomy Systems; Percutaneous Transluminal Angioplasty (PTA) Catheters; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices. Self-expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents, Crossing Catheters, Re-entry Catheters.

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 17/06/2001
Effective Date: 10/10/2016
Latest Revision Date: 10/10/2016
Expiry Date: 16/12/2018

UKAS MANAGEMENT SYSTEMS 003

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Certificate No: MD 660553

Location	Registered Activities
ev3, Inc. 4600 Nathan Lane North Plymouth Minnesota 55442 USA	Design and manufacture of sterile medical devices: Guidewires; Snares, Microsnares, Snare Catheters and Microcatheters; Endovascular Catheters; Rotating Y-Connectors; Thrombectomy Devices; Atherectomy Systems; Percutaneous Transluminal Angioplasty (PTA) Catheters; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices. Self-expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents, Crossing Catheters, Re-entry Catheters.
ev3, Inc. 3033 Campus Drive Plymouth Minnesota 55441 USA	Design and manufacture of sterile medical devices: Guidewires; Snares, Microsnares, Snare Catheters and Microcatheters; Endovascular Catheters; Rotating Y-Connectors; Thrombectomy Devices; Atherectomy Systems; Percutaneous Transluminal Angioplasty (PTA) Catheters; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices. Self-expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents, Crossing Catheters, Re-entry Catheters.
ev3, Inc. 2300 Berkshire Lane Plymouth Minnesota 55441 USA	Design and manufacture of sterile medical devices: Guidewires; Snares, Microsnares, Snare Catheters and Microcatheters; Endovascular Catheters; Rotating Y-Connectors; Thrombectomy Devices; Atherectomy Systems; Percutaneous Transluminal Angioplasty (PTA) Catheters; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices. Self-expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents, Crossing Catheters, Re-entry Catheters.

Original Registration Date: 17/06/2001

Effective Date: 10/10/2016

Latest Revision Date: 10/10/2016

Expiry Date: 16/12/2018

EC Design Examination Certificate

according the directive 93/42/EEC, Annex II (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

Invatec S.p.A.

Via Martiri della Libertà 7, 25030 Roncadelle (BS), Italy

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC Annex II.4 as documented in the report mentioned in the annex.

Product: PTA Catheter: Pacific Xtreme

This certificate is valid from 2018-02-16 to 2023-02-15

Registration No.: 50251-23-N5

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565 Stuttgart

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-02-23
Notified Body ID-number: 0124

Annex to the EC Design Examination Certificate No. 50251-23-N5

Revision status: 0

valid from 2018-02-16 to 2023-02-15

Report number: 50251-P15-05

Product: PTA Catheter: Pacific Xtreme

Intended use:

The Pacific Xtreme is indicated for percutaneous transluminal angioplasty (PTA) in patients with obstructive disease of peripheral arteries, i.e. Ilio-femoral-, femoral-, popliteal-, infra-popliteal- and renal arteries and for carotid and supra-aortic applications.

Pacific Xtreme for carotid and supra-aortic applications: only balloon catheters with diameters from 2 to 7 mm and lengths from 20 to 40 mm are indicated for carotid and supra-aortic applications with the exception of catheters with a usable length of 180 cm.

Technical data:

Balloon diameter (mm)	2,0 / 2,5 / 3,0 / 3,5 / 4,0 / 4,5 / 5,0 / 5,5 / 6,0 / 6,5 / 7,0
Balloon Length (mm)	Supra aortic use: 20, 30, 40 Non Supra aortic use: 20, 30, 40, 60, 80, 120, 150, 200, 250, 300
Catheter length, usable (cm)	Supra aortic use: 90 and 130 Non Supra aortic use: 90 - 130 - 180
Article codes	PCF 020 020 090*, PCF 020 020 130*, PCF 020 020 180, PCF 020 030 090*, PCF 020 030 130*, PCF 020 030 180, PCF 020 040 090*, PCF 020 040 130*, PCF 020 040 180, PCF 020 060 090, PCF 020 060 130, PCF 020 060 180, PCF 020 080 090, PCF 020 080 130, PCF 020 080 180, PCF 020 120 090, PCF 020 120 130, PCF 020 120 180, PCF 020 150 090, PCF 020 150 130, PCF 020 150 180
	PCF 025 020 090*, PCF 025 020 130*, PCF 025 020 180, PCF 025 030 090*, PCF 025 030 130*, PCF 025 030 180, PCF 025 040 090*, PCF 025 040 130*, PCF 025 040 180, PCF 025 060 090, PCF 025 060 130, PCF 025 060 180, PCF 025 080 090, PCF 025 080 130, PCF 025 080 180, PCF 025 120 090, PCF 025 120 130, PCF 025 120 180, PCF 025 150 090, PCF 025 150 130, PCF 025 150 180
	PCF 030 020 090*, PCF 030 020 130*, PCF 030 020 180, PCF 030 030 090*, PCF 030 030 130*, PCF 030 030 180, PCF 030 040 090*, PCF 030 040 130*, PCF 030 040 180, PCF 030 060 090, PCF 030 060 130, PCF 030 060 180, PCF 030 080 090, PCF 030 080 130, PCF 030 080 180, PCF 030 120 090, PCF 030 120 130, PCF 030 120 180, PCF 030 150 090, PCF 030 150 130, PCF 030 150 180
	PCF 035 020 090*, PCF 035 020 130*, PCF 035 020 180, PCF 035 030 090*, PCF 035 030 130*, PCF 035 030 180, PCF 035 040 090*, PCF 035 040 130*, PCF 035 040 180, PCF 035 060 090, PCF 035 060 130, PCF 035 060 180, PCF 035 080 090, PCF 035 080 130, PCF 035 080 180, PCF 035 120 090, PCF 035 120 130, PCF 035 120 180, PCF 035 150 090, PCF 035 150 130, PCF 035 150 180

* also for supraaortic application

Annex to the EC Design Examination Certificate No. 50251-23-N5

Revision status: 0

valid from 2018-02-16 to 2023-02-15

Article codes	PCF 040 020 090*, PCF 040 020 130*, PCF 040 020 180, PCF 040 030 090* PCF 040 030 130*, PCF 040 030 180, PCF 040 040 090*, PCF 040 040 130* PCF 040 040 180, PCF 040 060 090, PCF 040 060 130, PCF 040 060 180 PCF 040 080 090, PCF 040 080 130, PCF 040 080 180, PCF 040 120 090 PCF 040 120 130, PCF 040 120 180, PCF 040 150 090, PCF 040 150 130 PCF 040 150 180, PCF 040 200 090, PCF 040 200 130, PCF 040 250 090 PCF 040 250 130, PCF 040 300 090, PCF 040 300 130
	PCF 045 020 090*, PCF 045 020 130*, PCF 045 020 180, PCF 045 030 090* PCF 045 030 130*, PCF 045 030 180, PCF 045 040 090*, PCF 045 040 130* PCF 045 040 180, PCF 045 060 090, PCF 045 060 130, PCF 045 060 180 PCF 045 080 090, PCF 045 080 130, PCF 045 080 180, PCF 045 120 090 PCF 045 120 130, PCF 045 120 180, PCF 045 150 090, PCF 045 150 130 PCF 045 150 180
	PCF 050 020 090*, PCF 050 020 130*, PCF 050 020 180, PCF 050 030 090* PCF 050 030 130*, PCF 050 030 180, PCF 050 040 090*, PCF 050 040 130* PCF 050 040 180, PCF 050 060 090, PCF 050 060 130, PCF 050 060 180 PCF 050 080 090, PCF 050 080 130, PCF 050 080 180, PCF 050 120 090 PCF 050 120 130, PCF 050 120 180, PCF 050 150 090, PCF 050 150 130 PCF 050 150 180, PCF 050 200 090, PCF 050 200 130, PCF 050 250 090 PCF 050 250 130, PCF 050 300 090, PCF 050 300 130
	PCF 055 020 090*, PCF 055 020 130*, PCF 055 020 180, PCF 055 030 090* PCF 055 030 130*, PCF 055 030 180, PCF 055 040 090*, PCF 055 040 130* PCF 055 040 180, PCF 055 060 090, PCF 055 060 130, PCF 055 060 180 PCF 055 080 090, PCF 055 080 130, PCF 055 080 180, PCF 055 120 090 PCF 055 120 130, PCF 055 120 180
	PCF 060 020 090*, PCF 060 020 130*, PCF 060 020 180, PCF 060 030 090* PCF 060 030 130*, PCF 060 030 180, PCF 060 040 090*, PCF 060 040 130* PCF 060 040 180, PCF 060 060 090, PCF 060 060 130, PCF 060 060 180 PCF 060 080 090, PCF 060 080 130, PCF 060 080 180, PCF 060 120 090 PCF 060 120 130, PCF 060 120 180, PCF 060 150 090, PCF 060 150 130 PCF 060 200 090, PCF 060 200 130, PCF 060 250 090, PCF 060 250 130 PCF 060 300 090, PCF 060 300 130
	PCF 065 020 090*, PCF 065 020 130*, PCF 065 020 180, PCF 065 030 090* PCF 065 030 130*, PCF 065 030 180, PCF 065 040 090*, PCF 065 040 130* PCF 065 040 180, PCF 065 060 090, PCF 065 060 130, PCF 065 060 180 PCF 065 080 090, PCF 065 080 130, PCF 065 080 180, PCF 065 120 090 PCF 065 120 130, PCF 065 120 180
	PCF 070 020 090*, PCF 070 020 130* PCF 070 020 180, PCF 070 030 090* PCF 070 030 130*, PCF 070 030 180, PCF 070 040 090* PCF 070 040 130* PCF 070 040 180, PCF 070 060 090, PCF 070 060 130, PCF 070 060 180 PCF 070 080 090, PCF 070 080 130, PCF 070 080 180, PCF 070 120 090 PCF 070 120 130, PCF 070 120 180, PCF 070 150 090, PCF 070 150 130 PCF 070 200 090, PCF 070 200 130, PCF 070 250 090, PCF 070 250 130

* also for supraaortic application

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-02-23
Notified Body ID-number: 0124

EC DECLARATION OF CONFORMITY
Form F-5175

Conformity Assessment Route	**Annex II, Full Quality Assurance (excluding section II.4)** EC Certificate US00/51647.01 (SGS) ISO Certificate MD 660553 (BSI)
Approved Indications	**Peripheral**: The stent is indicated for use in occlusions, lesions at high risk for abrupt closure or threatened closure following percutaneous transluminal angioplasty (PTA); or lesions believed to be at high risk for restenosis, following PTA in the common iliac, external iliac, or subclavian arteries. **Biliary**: The stent is intended as a palliative treatment of malignant neoplasms in the biliary tree.

Product	**Protégé™ EverFlex™ Self-Expanding Peripheral Stent System**			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	20 January 2006			
Product Codes				
PRP35-06-020-080	PRP35-08-030-080	PRP35-08-100-120	PRP35-07-020-120	
PRP35-06-030-080	PRP35-08-040-080	PRP35-07-030-120	PRP35-08-120-120	
PRP35-06-040-080	PRP35-08-060-080	PRP35-07-060-120	PRP35-08-150-120	
PRP35-06-060-080	PRP35-08-080-080	PRP35-07-080-120		
PRP35-06-080-080	PRP35-08-100-080	PRP35-07-040-120		
PRP35-06-100-080	PRP35-06-020-120	PRP35-07-100-120		
PRP35-07-020-080	PRP35-06-030-120	PRP35-07-120-120		
PRP35-07-030-080	PRP35-06-040-120	PRP35-07-150-120		
PRP35-07-040-080	PRP35-06-060-120	PRP35-08-020-120		
PRP35-07-060-080	PRP35-06-080-120	PRP35-08-030-120		
PRP35-07-080-080	PRP35-06-100-120	PRP35-08-040-120		
PRP35-07-100-080	PRP35-06-120-120	PRP35-08-060-120		
PRP35-08-020-080	PRP35-06-150-120	PRP35-08-080-120		

Product	**Protégé™ EverFlex™ Self-Expanding Peripheral Stent System**			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	04 October 2007			
Product Codes				
PRP35-05-020-080	PRP35-05-020-120	PRP35-05-030-080	PRP35-05-030-120	
PRP35-05-040-080	PRP35-05-040-120	PRP35-05-060-080	PRP35-05-060-120	
PRP35-05-080-080	PRP35-05-080-120	PRP35-05-100-080	PRP35-05-100-120	

Product	**Protégé™ EverFlex™ Self-Expanding Peripheral Stent System**			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	08 November 2007			
Product Codes				
PRP35-06-120-080	PRP35-07-120-080	PRP35-08-120-080		
PRP35-06-150-080	PRP35-07-150-080	PRP35-08-150-080		

Product	Protégé™ EverFlex™ Self-Expanding Peripheral Stent System		
Class-Rule	Class IIb, Annex IX, Rule 8		
Date CE Mark Affixed	23 January 2008		
Product Codes			
PRP35DR-06-200-120*	PRP35DR-07-200-120*	PRP35DR-08-200-120*	*Note: EverFlex 200s are not used in biliary indications.

Product	Protégé™ EverFlex™ Self-Expanding Peripheral Stent System			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	23 April 2008			
Product Codes				
PRP35-05-120-080	PRP35-05-120-120	PRP35-05-150-080	PRP35-05-150-120	

Product	Protégé™ EverFlex™ Self-Expanding Biliary Stent System			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	20 January 2006			
Product Codes				
PRB35-06-020-080	PRB35-08-030-080	PRB35-07-020-120	PRB35-08-100-120	
PRB35-06-030-080	PRB35-08-040-080	PRB35-07-030-120	PRB35-08-120-120	
PRB35-06-040-080	PRB35-08-060-080	PRB35-07-060-120	PRB35-08-150-120	
PRB35-06-060-080	PRB35-08-080-080	PRB35-07-080-120		
PRB35-06-080-080	PRB35-08-100-080	PRB35-07-040-120		
PRB35-06-100-080	PRB35-06-020-120	PRB35-07-100-120		
PRB35-07-020-080	PRB35-06-030-120	PRB35-07-120-120		
PRB35-07-030-080	PRB35-06-040-120	PRB35-07-150-120		
PRB35-07-040-080	PRB35-06-060-120	PRB35-08-020-120		
PRB35-07-060-080	PRB35-06-080-120	PRB35-08-030-120		
PRB35-07-080-080	PRB35-06-100-120	PRB35-08-040-120		
PRB35-07-100-080	PRB35-06-120-120	PRB35-08-060-120		
PRB35-08-020-080	PRB35-06-150-120	PRB35-08-080-120		

Product	Protégé™ EverFlex™ Self-Expanding Biliary Stent System			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	04 October 2007			
Product Codes				
PRB35-05-020-080	PRB35-05-020-120	PRB35-05-030-080	PRB35-05-030-120	
PRB35-05-040-080	PRB35-05-040-120	PRB35-05-060-080	PRB35-05-060-120	
PRB35-05-080-080	PRB35-05-080-120	PRB35-05-100-080	PRB35-05-100-120	

EC DECLARATION OF CONFORMITY
Form F-5175

Product	**Protégé™ EverFlex™ Self-Expanding Biliary Stent System**			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	08 November 2007			
Product Codes				
PRB35-06-120-080	PRB35-07-120-080	PRB35-08-120-080		
PRB35-06-150-080	PRB35-07-150-080	PRB35-08-150-080		

Product	**Protégé™ EverFlex™ Self-Expanding Biliary Stent System**			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	23 April 2008			
Product Codes				
PRB35-05-120-080	PRB35-05-120-120			

Manufacturer (Name and Address)

ev3, Inc.
4600 Nathan Lane North
Plymouth, MN 55442 USA

Notified Body:

SGS United Kingdom Ltd
Systems & Services Certification
(Product Certification)
202B Worle Parkway
Weston-super-Mare
BS22 6WA UK
Notified Body Number: 0120

European Representative:

Covidien Ireland Limited
IDA Business & Technology Park,
Tullamore

We herewith declare that the above-mentioned products are in conformity with provisions of the Council Directive: 93/42/EEC of June 1993 as amended by Directive 2007/47/EC and applicable standards for medical devices. The list of applicable standards for the products identified above is maintained in technical documentation of the device.

All supporting documentation is retained under the premises of the manufacturer.

David Worrell
Senior Director Regulatory Affairs

Plymouth, Minnesota USA
Place of Issue

20 OCT 2016
Date of Issue

EC DECLARATION OF CONFORMITY
Form F-5175

Conformity Assessment Route	**Annex II, Full Quality Assurance** EC Certificates US00/51647.01, US05/64921 (SGS) ISO Certificate MD 660553 (BSI)
Approved Indications	Peripheral (all sizes excluding Tapered Stents): The stent is indicated for use in occlusions, lesions at high risk for abrupt closure or threatened closure following percutaneous transluminal angioplasty (PTA); or lesions believed to be at high risk for restenosis following PTA in the common iliac, external iliac, or subclavian arteries. Stenting is intended to improve and maintain artery luminal diameter. Carotid: The stent is indicated for treatment of stenoses of the common carotid artery (CCA), internal carotid artery (ICA) and carotid bifurcation.

Product	**Protege™ RX Self-Expanding Peripheral Stent System (Tapered)**			
Class-Rule	Class III (carotid), Annex IX, Rule 8			
Date CE Mark Affixed	28 April 2005			
Product Codes				
SEPX-8-6-30-135	SEPX-8-6-40-135	SEPX-10-7-30-135	SEPX-10-7-40-135	

Product	**Protege™ RX Self-Expanding Peripheral Stent System**			
Class-Rule	Class III (carotid), Annex IX, Rule 8			
Date CE Mark Affixed	07 June 2005			
Product Codes				
SEPX-6-20-135	SEPX-6-30-135	SEPX-6-40-135	SEPX-6-60-135	SEPX-7-20-135
SEPX-7-30-135	SEPX-7-40-135	SEPX-7-60-135	SEPX-8-20-135	SEPX-8-30-135
SEPX-8-40-135	SEPX-8-60-135	SEPX-9-20-135	SEPX-9-30-135	SEPX-9-40-135
SEPX-9-60-135	SEPX-10-20-135	SEPX-10-30-135	SEPX-10-40-135	SEPX-10-60-135

Manufacturer (Name and Address)

ev3, Inc.
4600 Nathan Lane North
Plymouth, MN 55442 USA

Notified Body:

SGS United Kingdom Ltd
Systems & Services Certification
(Product Certification)
202B Worle Parkway
Weston-super-Mare
BS22 6WA UK
Notified Body Number: 0120

European Representative:

Covidien Ireland Limited
IDA Business & Technology Park,
Tullamore

We herewith declare that the above-mentioned products are in conformity with provisions of the Council Directive: 93/42/EEC of June 1993 as amended by Directive 2007/47/EC and applicable standards for medical devices. The list of applicable standards for the products identified above is maintained in technical documentation of the device.

All supporting documentation is retained under the premises of the manufacturer.

David Worrell
Senior Director Regulatory Affairs

Plymouth, Minnesota USA
Place of Issue

20 OCT 2016
Date of Issue

EC Design Examination Certificate: Certificate US05/64921

ev3, Inc.

4600 Nathan Lane North,
Plymouth, MN, 55442, United States

Device Identification:

Protégé™ RX Self-Expanding Peripheral Stent System

Intended Purpose of Device:

Carotid - The stent is indicated for treatment of stenoses of the common carotid artery (CCA), internal carotid artery (ICA), and carotid bifurcation.

Peripheral - The stent is indicated for use in occlusions, lesions at high risk for abrupt closure or threatened closure following percutaneous transluminal angioplasty (PTA); or lesions believed to be at high risk for restenosis following PTA in the common iliac, external iliac, or subclavian arteries. Stenting is intended to improve and maintain artery luminal diameter.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 3 September 2015 until 11 March 2020
Issue 10

Certification is based on report number(s) WW/MC 212219 dated 2 August 2015

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum

Authorised by

SGS United Kingdom Limited, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS EC 01 0311

EC DECLARATION OF CONFORMITY

RD-NV001482 Rev. A

General Applicable Directives/Standards:

EN ISO 13485: 2012 + AC: 2012 — **Quality Management System Standard** (281863 MP2012)

93/42/EEC — **Council Directive Concerning Medical Devices**
Conformity Assessment Route — Annex II (Section 4) 393599 MRA
Annex II (excluding Section 4) 281863 MR2

Product	Model/Reference/Catalogue Number(s)				GMDN Code	Class-Rule	Date CE Mark Affixed
Axium Prime Detachable Coil System	**Axium Prime Bare – Helix configuration**				60940, Neurovascular Embolization Coil	Class III, Rule 8	07 June 2007
	APB-4-6-HX-SS	APB-4-12-HX-SS	APB-5-20-HX-SS				
	APB-4-8-HX-SS	APB-5-10-HX-SS	APB-6-12-HX-SS				
	APB-4-10-HX-SS	APB-5-15-HX-SS	APB-6-20-HX-SS				
	APB-1-1-HX-ES	APB-1.5-4-HX-ES	APB-2-8-HX-ES	APB-3-6-HX-ES	60940, Neurovascular Embolization Coil	Class III, Rule 8	25 January 2016
	APB-1-2-HX-ES	APB-2-1-HX-ES	APB-2.5-3-HX-ES	APB-3-8-HX-ES			
	APB-1-3-HX-ES	APB-2-2-HX-ES	APB-2.5-4-HX-ES	APB-3-10-HX-ES			
	APB-1.5-1-HX-ES	APB-2-3-HX-ES	APB-2.5-6-HX-ES				
	APB-1.5-2-HX-ES	APB-2-4-HX-ES	APB-2.5-8-HX-ES				
	APB-1.5-3-HX-ES	APB-2-6-HX-ES	APB-3-4-HX-ES				
	Axium Prime Bare – 3D configuration				60940, Neurovascular Embolization Coil	Class III, Rule 8	07 June 2007
	APB-4-6-3D-SS	APB-4-12-3D-SS	APB-5-15-3D-SS	APB-6-20-3D-SS			
	APB-4-8-3D-SS	APB-5-8-3D-SS	APB-6-10-3D-SS				
	APB-4-10-3D-SS	APB-5-10-3D-SS	APB-6-15-3D-SS				
	APB-1-2-3D-ES	APB-1.5-4-3D-ES	APB-2.5-6-3D-ES	APB-3.5-8-3D-ES	60940, Neurovascular Embolization Coil	Class III, Rule 8	25 January 2016
	APB-1-3-3D-ES	APB-2-2-3D-ES	APB-3-4-3D-ES	APB-3.5-10-3D-ES			
	APB-1-4-3D-ES	APB-2-3-3D-ES	APB-3-6-3D-ES				
	APB-1.5-2-3D-ES	APB-2-4-3D-ES	APB-3-8-3D-ES				
	APB-1.5-3-3D-ES	APB-2.5-4-3D-ES	APB-3.5-6-3D-ES				
	FC-3-6-3D	FC-5-8-3D	FC-7-30-3D	FC-12-50-3D	60940, Neurovascular Embolization Coil	Class III, Rule 8	08 June 2017
	FC-3-8-3D	FC-5-10-3D	FC-8-15-3D	FC-14-30-3D			
	FC-3-10-3D	FC-5-15-3D	FC-8-20-3D	FC-14-40-3D			
	FC-3.5-6-3D	FC-5-20-3D	FC-8-30-3D	FC-14-50-3D			

	FC-3.5-8-3D	FC-6-10-3D	FC-9-20-3D	FC-16-40-3D			
	FC-3.5-10-3D	FC-6-15-3D	FC-9-30-3D	FC-16-50-3D			
	FC-4-6-3D	FC-6-20-3D	FC-10-20-3D	FC-18-40-3D			
	FC-4-8-3D	FC-6-25-3D	FC-10-30-3D	FC-18-50-3D			
	FC-4-10-3D	FC-7-12-3D	FC-10-40-3D	FC-20-50-3D			
	FC-4-12-3D	FC-7-15-3D	FC-12-30-3D	FC-22-50-3D			
	FC-4-15-3D	FC-7-20-3D	FC-12-40-3D	FC-25-50-3D			
Instant Detacher	ID-1-5				60637 Vascular embolization coil detacher, single-use	Class 1s, Rule 1	07 June 2007

Manufacturer:
Micro Therapeutics, Inc.
DBA ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main,
Germany
Notified Body Number: 0297

European Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the medical device directive 93/42/EEC as amended by 2007/47/EC and EN ISO 13485: 2012 + AC: 2012. All supporting documentation is retained under the premises of the manufacturer.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Sanjay Sharma
Sr. Manager, Regulatory Affairs

Irvine, California 92618; USA
Place of Issue

29 Nov 2017
Date of Issue

This Declaration of Conformity expires on 2022-03-11.

EC DECLARATION OF CONFORMITY

RD-NV001522 Rev. B

General Applicable Directives/Standards:

EN ISO 13485: 2012 + AC: 2012 **Quality Management System Standard** (281863 MP2012)

93/42/EEC **Council Directive Concerning Medical Devices**
Conformity Assessment Route Annex II (Section 4) 489865 MRA
Annex II (excluding Section 4) 281863 MR2

Product	Model/Reference/ Catalogue Number(s)	GMDN Code	Class-Rule	Date CE Mark Affixed
Mirage™ .008 Hydrophilic Guidewire	103-0608	58115 Peripheral Vascular Guidewire	Class III, Rule 7	31-DEC-2003
SilverSpeed™ -10 Hydrophilic Guidewire	103-0601-200	58115 Peripheral Vascular Guidewire	Class III, Rule 7	31-DEC-2003
SilverSpeed™ -14 Hydrophilic Guidewire	103-0602-175 103-0602-200	58115 Peripheral Vascular Guidewire	Class III, Rule 7	31-DEC-2003
SilverSpeed™ -16 Hydrophilic Guidewire	103-0603-200	58115 Peripheral Vascular Guidewire	Class III, Rule 7	31-DEC-2003
X-pedion™ -10 Hydrophilic Guidewire	103-0605-200	58115 Peripheral Vascular Guidewire	Class III, Rule 7	31-DEC-2003
X-pedion™-14 Hydrophilic Guidewire	203-0602-200	58115 Peripheral Vascular Guidewire	Class III, Rule 7	31-DEC-2003
Avigo™ Hydrophilic Guidewire	103-0606-200	58115 Peripheral Vascular Guidewire	Class III, Rule 7	15-OCT-2012

Manufacturer:
Micro Therapeutics, Inc.
DBA ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main,
Germany
Notified Body Number: 0297

European Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the medical device directive 93/42/EEC as amended by 2007/47/EC and EN ISO 13485: 2012 + AC: 2012. All supporting documentation is retained under the premises of the manufacturer.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Analia Staubly
Manager, Regulatory Affairs

Irvine, California 92618; USA
Place of Issue

24JUL18
Date of Issue

This Declaration of Conformity expires on 2021-OCT-31.

EC DECLARATION OF CONFORMITY

RD-NV001525 Rev. A

General Applicable Directives/Standards:

EN ISO 13485: 2012 + AC: 2012	**Quality Management System Standard** (281863 MP2012)
93/42/EEC **Conformity Assessment Route**	**Council Directive Concerning Medical Devices** Annex II (Section 4) 499969 MRA Annex II (excluding Section 4) 281863 MR2

Product	Model/Reference/ Catalogue Number(s)	GMDN Code	Class-Rule	Date CE Mark Affixed
Navien™ A+ Intracranial Support Catheter	RFXA058-105-08	17846 Vascular Guide-Catheter, Single-Use	Class III, Rule 7	12-DEC-2012
	RFXA058-115-08			
	RFXA058-125-08			
	RFXA058-130-08			
	RFXA072-95-08			
	RFXA072-95-08MP			
	RFXA072-105-08			
	RFXA072-105-08MP			
	RFXA072-115-08			
	RFXA072-115-08MP			
	RFXA072-125-08			
	RFXA072-125-08MP			
	RFXA072-130-08			
	RFXA072-130-08MP			

Manufacturer:
Micro Therapeutics, Inc.
DBA ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 US

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main,
Germany
Notified Body Number: 0297

European Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the medical device directive 93/42/EEC as amended by 2007/47/EC and EN ISO 13485: 2012 + AC: 2012. All supporting documentation is retained under the premises of the manufacturer.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Analia Staubly
Manager, Regulatory Affairs

Irvine, California 92618; USA
Place of Issue

22 DEC 17
Date of Issue

This Declaration of Conformity expires on 2019-JUL-12.

EC DECLARATION OF CONFORMITY

RD-NV001532 Rev. A

General Applicable Directives/Standards:

EN ISO 13485: 2012 + AC: 2012 **Quality Management System Standard** (281863 MP2012)

93/42/EEC **Council Directive Concerning Medical Devices**
Conformity Assessment Route Annex II (Section 4) 528000 MRA
Annex II (excluding Section 4) 281863 MR2

Product	Model/Reference/ Catalogue Number(s)	GMDN Code	Class-Rule	Date CE Mark Affixed
Solitaire™ Platinum Revascularization Device	SRD3-4-20-10	58173 Embolectomy/ Thrombectomy Suction Catheter	Class III, Rule 7	5-MAR-2016
	SRD3-4-40-10			
	SRD3-6-20-10			
	SRD3-6-40-10			
	SRD3-4-20-05			16-SEP-2016
	SRD3-6-24-06			

Manufacturer:
Micro Therapeutics, Inc.
DBA ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main,
Germany
Notified Body Number: 0297

European Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the medical device directive 93/42/EEC as amended by 2007/47/EC and EN ISO 13485: 2012 + AC: 2012. All supporting documentation is retained under the premises of the manufacturer.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Analia Staubly
Manager, Regulatory Affairs

Irvine, California 92618; USA
Place of Issue

03JAN18
Date of Issue

This Declaration of Conformity expires on 2021-03-04

EC DECLARATION OF CONFORMITY
Form F-5175

Conformity Assessment Route	**Annex II, Full Quality Assurance** EC Certificates US00/51647.01, US02/56826 ISO Certificate US01/52678
Approved Indications	The SpiderFX Embolic Protection Device provides distal embolization protection during general vascular use, including peripheral, coronary, and carotid interventions.

Product	**SpiderFX™ Embolic Protection Device**			
Class-Rule	Class III, Annex IX, Rule 6, indent 1			
Date CE Mark Affixed	21 December 2006			
Product Codes				
SPD2-030-190	SPD2-040-190	SPD2-050-190	SPD2-060-190	SPD2-070-190
SPD2-030-320	SPD2-040-320	SPD2-050-320	SPD2-060-320	SPD2-070-320

Manufacturer (Name and Address)

ev3, Inc.
4600 Nathan Lane North
Plymouth, MN 55442 USA

Notified Body:

SGS United Kingdom Ltd
Systems & Services Certification
(Quality System)
202B Worle Parkway
Weston-super-Mare
BS22 6WA UK
Notified Body Number: 0120

European Representative:

Covidien Ireland Limited
IDA Business & Technology Park,
Tullamore

We herewith declare that the above-mentioned products are in conformity with provisions of the Council Directive: 93/42/EEC of June 1993 as amended by Directive 2007/47/EC and applicable standards for medical devices. The list of applicable standards for the products identified above is maintained in technical documentation of the device.

All supporting documentation is retained under the premises of the manufacturer.

David Worrell
Senior Director Regulatory Affairs

Plymouth, Minnesota USA
Place of Issue

10 MAR 2016
Date of Issue

EC DECLARATION OF CONFORMITY
Form F-5175

Conformity Assessment Route	**Annex II, Full Quality Assurance** EC Certificates US00/51647.01, US02/56826 (SGS) ISO Certificate MD 660553 (BSI)
Approved Indications	The SpiderFX Embolic Protection Device provides distal embolization protection during general vascular use, including peripheral, coronary, and carotid interventions.

Product	**SpiderFX™ Embolic Protection Device**			
Class-Rule	Class III, Annex IX, Rule 6, indent 1			
Date CE Mark Affixed	21 December 2006			
Product Codes				
SPD2-030-190	SPD2-040-190	SPD2-050-190	SPD2-060-190	SPD2-070-190
SPD2-030-320	SPD2-040-320	SPD2-050-320	SPD2-060-320	SPD2-070-320

Manufacturer (Name and Address)

ev3, Inc.
4600 Nathan Lane North
Plymouth, MN 55442 USA

Notified Body:

SGS United Kingdom Ltd
Systems & Services Certification
(Product Certification)
202B Worle Parkway
Weston-super-Mare
BS22 6WA UK
Notified Body Number: 0120

European Representative:

Covidien Ireland Limited
IDA Business & Technology Park,
Tullamore

We herewith declare that the above-mentioned products are in conformity with provisions of the Council Directive: 93/42/EEC of June 1993 as amended by Directive 2007/47/EC and applicable standards for medical devices. The list of applicable standards for the products identified above is maintained in technical documentation of the device.

All supporting documentation is retained under the premises of the manufacturer.

David Worrell
Senior Director Regulatory Affairs

Plymouth, Minnesota USA
Place of Issue

20 OCT 2016
Date of Issue

EC Certificate - Full Quality Assurance System

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

No. **CE 684995**

Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Design, Development and Manufacture of Sterile Self-expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-12-20** Date: **2017-12-20** Expiry Date: **2020-12-16**

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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 684995**
Date:	**2017-12-20**
Issued To:	**ev3, Inc.** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
ev3, Inc. 2300 Berkshire Lane Plymouth Minnesota 55441 USA	**Design** **Development**
ev3, Inc. 3033 Campus Drive Plymouth Minnesota 55441 USA	**Clinical Studies** **Regulatory Compliance**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 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 684995**
Date:	**2017-12-20**
Issued To:	**ev3, Inc.** **4600 Nathan Lane North** **Plymouth** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 684995**
Date: **2017-12-20**
Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
Current	8863804	First Issue – Transfer from another Notified Body.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

STERIS Isomedix Services
1880 Industrial Drive
Libertyville
Illinois
60048
USA

Holds Certificate Number: MD 89745

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.
The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.

For and on behalf of BSI:

Pietro Foschi - Strategic Delivery Director

Originally registered: 13/10/2004 Latest Issue: 17/02/2015 Expiry Date: 12/03/2018

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Certificate No: MD 89745

Location	Registered Activities
STERIS Isomedix Services Business Unit Level Headquarters 1880 Industrial Drive Libertyville Illinois 60048 USA	Group Level Headquarters.
STERIS Isomedix Services North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	The provision of a contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.
STERIS Isomedix Services 1175 Isuzu Parkway Grand Prairie Texas 75050 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.
STERIS Isomedix Services Inc 7685 Saint Andrews Avenue San Diego California 92154 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.
STERIS Isomedix Services 1435 Isomedix Place El Paso Texas 79936 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007. The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.

Originally registered: 13/10/2004 Latest Issue: 17/02/2015 Expiry Date: 12/03/2018

Certificate No: MD 89745

Location	Registered Activities
STERIS Isomedix Services 4405 Marketing Place Groveport Ohio 43125 USA	The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 2500 Commerce Drive Libertyville Illinois 60048 USA	The provision of contract gamma irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.
STERIS Isomedix Services 435 Whitney Street Northborough Massachusetts 01532 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007. The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 1000 S. Sarah Place Ontario California 91761 USA	The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 9120 South 150 East Sandy Utah 84070 USA	The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.

Originally registered: 13/10/2004 Latest Issue: 17/02/2015 Expiry Date: 12/03/2018

Certificate No: MD 89745

Location	Registered Activities
STERIS Isomedix Services 2072 Southport Road Spartanburg South Carolina 29306 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007. The provision of a contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 43425 Business Park Drive Temecula California 92590 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.
STERIS Isomedix Services State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 9 Apollo Drive Whippany New Jersey 07981 USA	The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 184 Crown Court Whitby Ontario L1N 7B1 Canada	The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.
STERIS Isomedix Services 23 Elizabeth Drive Chester New York 10918 USA	The provision of a contract irradiation sterilization service in accordance with EN ISO 11137-1:2006.

Originally registered: 13/10/2004 Latest Issue: 17/02/2015 Expiry Date: 12/03/2018

Certificate No: MD 89745

Location	Registered Activities
STERIS Isomedix Services 1441 Don Haskins Drive El Paso Texas 79936 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.

Originally registered: 13/10/2004 Latest Issue: 17/02/2015 Expiry Date: 12/03/2018

Declaration of Conformity

Legal Manufacturer:	ev3, Inc. 4600 Nathan Lane North Plymouth, MN 55442 USA
EC Authorized Representative	Medtronic Ireland Parkmore Business Park West Galway Ireland
Design Facility:	Medtronic, Inc. (formerly d.b.a. ev3, Inc.) 2300 Berkshire Lane North Plymouth, MN 55441 USA
Manufacturing Facility:	ev3, Inc. 4600 Nathan Lane North Plymouth, MN 55442 USA
Product Family/ies:	Support Catheters
Products:	TrailBlazer™ Angled Support Catheter
Classification:	Class IIa based on Annex IX, Rule 6 of Directive 93/42/EEC (MDD)
Notified Body	BSI Group Kitemark Court, Davy Avenue Knowlhill, Milton Keynes, MK5 8PP Notified Body Number: 0086
Quality Management Systems Certificate	MD 660553
EC Certificate- Full Quality Assurance	CE 684995
EC Design Certificate	Not applicable

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), including amendments issued, which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by the MDD, Annex II.3 Approval.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Plymouth, Minnesota, USA Date: Aug. 2, 2018

Name: Monika McDole-Russell

Title Regulatory Affairs Manager Signature Monika McDole-Russell

Products:

Product	TrailBlazer™ Angled Support Catheter			
Class-Rule	Class IIa, Rule 6, Annex IX			
Date CE Mark Affixed	November 7, 2016			
Product Codes				
ASC-014-090	ASC-014-135	ASC-014-150	ASC-018-090	ASC-018-135
ASC-018-150	ASC-035-065	ASC-035-090	ASC-035-135	ASC-035-150

Revision History

Revision	Date	Description of Change
B	30-Jul-2018	Update to new template, change notified body to BSI, update EU authorized rep, update ISO 13485 and EC quality certificate

Declaration of Conformity

Legal Manufacturer:	ev3, Inc. 4600 Nathan Lane North Plymouth, MN 55442 USA
EC Authorized Representative	Medtronic Ireland Parkmore Business Park West Galway Ireland
Design Facility:	Medtronic, Inc. (formerly d.b.a. ev3, Inc.) 2300 Berkshire Lane North Plymouth, MN 55441 USA
Manufacturing Facility:	ev3, Inc. 4600 Nathan Lane North Plymouth, MN 55442 USA
Product Family/ies:	Balloon expandable peripheral stents
Products:	Visi-Pro™ Balloon-expandable Peripheral Stent System
Classification:	Class IIb based on Annex IX, Rule 8 of Directive 93/42/EEC (MDD)
Notified Body	BSI
EC Quality Certificate	CE 684995
EC Design Certificate	Not applicable

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), including amendments issued, which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by the MDD, Annex II.3 Approval.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Plymouth, Minnesota, USA Date: 19 MAR 2018

Name: David Worrell

Title Sr. Regulatory Affairs Director Signature

Products:

Product	Visi-Pro™ Balloon-expandable Peripheral Stent System			
Class-Rule	Class IIb, Annex IX, Rule 8			
Date CE Mark Affixed	17 October 2007			
Product Codes				
PXP35-05-12-080	PXP35-05-17-080	PXP35-05-27-080	PXP35-05-37-080	PXP35-05-57-080
PXP35-06-12-080	PXP35-06-17-080	PXP35-06-27-080	PXP35-06-37-080	PXP35-06-57-080
PXP35-07-12-080	PXP35-07-17-080	PXP35-07-27-080	PXP35-07-37-080	PXP35-07-57-080
PXP35-08-17-080	PXP35-08-27-080	PXP35-08-37-080	PXP35-08-57-080	PXP35-09-17-080
PXP35-09-27-080	PXP35-09-37-080	PXP35-09-57-080	PXP35-10-17-080	PXP35-10-27-080
PXP35-10-37-080	PXP35-10-57-080			
PXP35-05-17-135	PXP35-05-27-135	PXP35-05-37-135	PXP35-05-57-135	PXP35-06-17-135
PXP35-06-27-135	PXP35-06-37-135	PXP35-06-57-135	PXP35-07-17-135	PXP35-07-27-135
PXP35-07-37-135	PXP35-07-57-135	PXP35-08-17-135	PXP35-08-27-135	PXP35-08-37-135
PXP35-08-57-135	PXP35-09-17-135	PXP35-09-27-135	PXP35-09-37-135	PXP35-09-57-135
PXP35-10-17-135	PXP35-10-27-135	PXP35-10-37-135	PXP35-10-57-135	

Revision History

Revision	Date	Description of Change
D	01-Mar-2018	Update to new template, change notified body to BSI, update EU authorized rep, update EC quality certificate.