



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 până la  
Prelungită până 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 autenticată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.





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.

  
Dumitru Popa  
Director filială „Stejaur”



Executor : Mariana Guzun  
Tel: 022 812 614

Filiala Nr. 1 „Stejaur”  
Bd. Ștefan cel Mare și Sfânt 196  
MD-2004, Chișinău, Moldova  
Cod MOBBMD22  
Cont de corespondență 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. Ștefan cel Mare și Sfânt 81a  
MD-2012, Chișinău, 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**

*Funcția, numele, prenumele persoanei  
care a eliberat certificatul*

*semnătura*

MD 0067985







„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 vânzarea 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  
tel. 022-266-252



**Lazari Aliona**



# OXIVIT-MED

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 |

**SITUAȚIILE FINANCIARE**

pentru perioada 01.01.2018 31.12.2018

Entitatea SC OXIVIT-MED SRL  
(Denumirea completă)

40424951

1007600044280

(Cod CUIIO)

(Cod IDNO)

Sediul: MD MD-2024 MUN.CHIȘINĂU; MUN.CHIȘINĂU SEC.BOTANICA 110

(Cod poștal)

Raionul (municipiul, UTA); Localitatea  
Decebal, 82, , of.90

Cod CUATM

strada, nr, bl.

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 și coordonatele al contabilului-șef: Dl (dna) Kojevnikov Dmitrii

Unitatea de măsură: leu

Tel. +37369200333

Anexa 8

**Notă informativă privind veniturile și cheltuielile clasificate după natură**

| Indicatori   | Cod rd. | Perioada de gestiune |            |
|--|---------|----------------------|------------|
|  |         | precedentă           | curentă    |
| 1  | 2       | 3                    | 4          |
| Venituri din vânzări   | 010     | 32.606.761           | 43.289.243 |
| Alte venituri din activitatea operațională   | 020     |                      | 209.007    |
| Venituri din alte activități   | 030     | 1.316.819            | 1.171.806  |
| <b>Total venituri</b> (rd.010 + rd.020 + rd.030)   | 040     | 33.923.580           | 44.670.056 |
| Variația stocurilor  | 050     |                      |            |
| Costul vânzării mărfurilor vândute   | 060     | 22.812.507           | 33.465.025 |
| Cheltuieli privind stocurile   | 070     |                      |            |
| Cheltuieli cu personalul privind remunerarea muncii  | 080     | 36.000               | 71.355     |
| Contribuții de asigurări sociale de stat obligatorii și prime de asigurare obligatorie de asistență medicală | 090     | 9.900                | 18.700     |
| Cheltuieli cu amortizarea și deprecierea activelor imobilizate   | 100     |                      | 2.139      |
| Alte cheltuieli  | 110     | 504.232              | 298.104    |
| Cheltuieli din alte activități   | 120     | 1.421.291            | 820.441    |
| <b>Total cheltuieli</b> (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  |

## BILANȚUL

la 31.12.2018

| Nr. cpt. | ACTIV   | Cod rd. | Sold la                         |                                 |
|----------|---|---------|---------------------------------|---------------------------------|
|          |   |         | Începutul perioadei de gestiune | Sfârșitul perioadei de gestiune |
| 1        | 2   | 3       | 4                               | 5                               |
| 1.       | <b>Active imobilizate</b>   |         |                                 |                                 |
|          | 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     |                                 |                                 |
|          | <b>Total active imobilizate</b><br>(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.       | <b>Active circulante</b>  |         |                                 |                                 |
|          | 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                           |
|          | <b>Total active circulante</b><br>(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                      |
|          | <b>Total active (rd.130 + rd.300)</b>   | 310     | 14.342.894                      | 22.082.283                      |

| Nr. cpt. | P A S I V  | Cod rd. | Sold la                         |                                 |
|----------|--|---------|---------------------------------|---------------------------------|
|          |  |         | Începutul perioadei de gestiune | Sfârșitul perioadei de gestiune |
| 1        | 2  | 3       | 4                               | 5                               |
| 3.       | <b>Capital propriu</b>   |         |                                 |                                 |
|          | Capital social și suplimentar  | 320     | 5.400                           | 5.400                           |
|          | Rezerve  | 330     |                                 |                                 |
|          | Corecții ale rezultatelor anilor precedenți  | 340     | X                               |                                 |
|          | Profit nerepartizat (pierdere neacoperită) al anilor precedenți  | 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     |                                 |                                 |
|          | <b>Total capital propriu</b><br>(rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)   | 390     | 9.289.541                       | 14.076.336                      |
| 4.       | <b>Datorii pe termen lung</b>  |         |                                 |                                 |
|          | 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     |                                 |                                 |
|          | <b>Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)</b>  | 440     | 76.630                          | 76.630                          |
| 5.       | <b>Datorii curente</b>   |         |                                 |                                 |
|          | Credite bancare pe termen scurt  | 450     |                                 |                                 |
|          | Împrumuturi pe termen scurt  | 460     |                                 |                                 |
|          | Datorii comerciale   | 470     | 4.314.663                       | 7.450.519                       |
|          | Datorii față de părțile afiliate   | 480     |                                 |                                 |
|          | Avansuri primite curente   | 490     | 219.377                         | 337.734                         |
|          | Datorii față de personal   | 500     | 2.054                           | 14.819                          |
|          | Datorii privind asigurările sociale și medicale  | 510     |                                 |                                 |
|          | Datorii față de buget  | 520     | 348.444                         | 62                              |
|          | Venituri anticipate curente  | 530     |                                 |                                 |
|          | Datorii față de proprietari  | 540     |                                 |                                 |
|          | Finanțări și încasări cu destinație specială curente   | 550     |                                 |                                 |
|          | Provizioane curente  | 560     |                                 |                                 |
|          | Alte datorii curente   | 570     | 92.185                          | 126.183                         |
|          | <b>Total datorii curente</b><br>(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                       |
|          | <b>Total pasive (rd.390 + rd.440 + rd.580)</b>   | 590     | 14.342.894                      | 22.082.283                      |



**SITUAȚIA DE PROFIT ȘI 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 vânzări  | 010     | 32.606.761           | 43.289.243 |
| Costul vânzărilor   | 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 (pierdere) (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

**SITUAȚIA 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 sfîrșitul perioadei de gestiune |
|---------|---|---------|---|-----------|-----------|---|
| 1       | 2   | 3       | 4                                       | 5         | 6         | 7                                       |
| 1       | <b>Capital social și suplimentar</b>  |         |   |           |           |   |
|         | Capital social  | 010     | 5.400                                   |           |           | 5.400                                   |
|         | Capital suplimentar   | 020     |   |           |           |   |
|         | Capital nevărsat  | 030     | 0                                       | 0         | 0         | 0                                       |
|         | Capital neînregistrat   | 040     |   |           |           |   |
|         | Capital retras  | 050     | 0                                       | 0         | 0         | 0                                       |
|         | <b>Total capital social și suplimentar</b><br>(rd.010 + rd.020 + rd.030 + rd.040 + rd.050)              | 060     | 5.400                                   |           |           | 5.400                                   |
| 2       | <b>Rezerve</b>  |         |   |           |           |   |
|         | Capital de rezervă  | 070     |   |           |           |   |
|         | Rezerve statutare   | 080     |   |           |           |   |
|         | Alte rezerve  | 090     |   |           |           |   |
|         | <b>Total rezerve</b> (rd.070 + rd.080 + rd.090)   | 100     |   |           |           |   |
| 3       | <b>Profit nerepartizat (pierdere neacoperită)</b>   |         |   |           |           |   |
|         | Corecții ale rezultatelor anilor precedenți   | 110     |   |           |           |   |
|         | Profit nerepartizat (pierdere neacoperită) al anilor precedenți   | 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                                       | 0         | 0         | 0                                       |
|         | Rezultatul din tranziția la noile reglementări contabile  | 150     |   |           |           |   |
|         | <b>Total profit nerepartizat (pierdere neacoperită)</b><br>(rd.110 + rd.120 + rd.130 + rd.140 + rd.150) | 160     | 9.284.141                               | 8.791.062 | 4.004.267 | 14.070.936                              |
| 4       | <b>Alte elemente de capital propriu, din care</b>   | 170     |   |           |           |   |
|         | Diferențe din reevaluare  | 171     |   |           |           |   |
|         | Subvenții entităților cu proprietate publică  | 172     |   |           |           |   |
|         | <b>Total capital propriu</b> (rd.060 + rd.100 + rd.160 + rd.170)  | 180     | 9.289.541                               | 8.791.062 | 4.004.267 | 14.076.336                              |

**SITUAȚIA 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          |
| <b>Fluxuri de numerar din activitatea operațională</b>   |         |                      |            |
| Încasări din vânzări   | 010     | 31.819.317           | 44.233.939 |
| Plăți pentru stocuri și servicii procurate   | 020     | 22.463.069           | 34.177.570 |
| Plăți către angajați și organe de asigurare socială și medicală  | 030     | 72.040               | 89.849     |
| Dobînzi plătite  | 040     |                      |            |
| Plata impozitului pe venit   | 050     | 767.369              | 2.090.569  |
| Alte încasări  | 060     |                      |            |
| Alte plăți   | 070     | 2.973.220            | 6.763.644  |
| <b>Fluxul net de numerar din activitatea operațională</b><br>(rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070 ) | 080     | 5.543.619            | 1.112.307  |
| <b>Fluxuri de numerar din activitatea de investiții</b>  |         |                      |            |
| Încasări din vânzarea activelor imobilizate  | 090     |                      |            |
| Plăți aferente intrărilor de active imobilizate  | 100     |                      |            |
| Dobînzi încasate   | 110     |                      |            |
| Dividende încasate   | 120     |                      |            |
| Alte încasări (plăți)  | 130     |                      |            |
| <b>Fluxul net de numerar din activitatea de investiții</b><br>(rd.090 – rd.100 + rd.110 + rd.120 ± rd.130)                   | 140     |                      |            |
| <b>Fluxuri de numerar din activitatea financiară</b>   |         |                      |            |
| Încasări sub formă de credite și împrumuturi   | 150     |                      |            |
| Plăți aferente rambursării creditelor și împrumuturilor  | 160     |                      |            |
| Dividende plătite  | 170     |                      |            |
| Încasări din operațiuni de capital   | 180     |                      |            |
| Alte încasări (plăți)  | 190     |                      |            |
| <b>Fluxul net de numerar din activitatea financiară</b> (rd.150 – rd.160 – rd.170 + rd.180 ± rd.190)                         | 200     |                      |            |
| <b>Fluxul net de numerar total</b><br>(± rd.080 ± rd.140 ± rd.200)   | 210     | 5.543.619            | 1.112.307  |
| Diferențe de curs valutar favorabile (nefavorabile)  | 220     | -918.567             | 38.680     |
| <b>Sold de numerar la începutul perioadei de gestiune</b>  | 230     | 1.969.026            | 6.594.078  |
| <b>Sold de numerar la sfârșitul perioadei de gestiune</b> (± rd.210 ± rd.220 + rd.230)                                       | 240     | 6.594.078            | 7.745.065  |

**Date generale**

1. Certificat de înregistrare a entității, 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 deținătorilor a cel puțin 20% \_\_\_\_\_ lei,

Modificări ulterioare:

a) \_\_\_\_\_, suma \_\_\_\_\_ lei, inclusiv cota statului \_\_\_\_\_ lei,

b) \_\_\_\_\_, suma \_\_\_\_\_ lei, inclusiv cota statului \_\_\_\_\_ lei,

3. Entitățile, activitatea cărora necesită licență, indică:

Licența în vigoare:

) Număr \_\_\_\_\_, data eliberării \_\_\_\_\_

Termen de valabilitate \_\_\_\_\_

Tipul de activitate \_\_\_\_\_

Organul care a eliberat licența \_\_\_\_\_

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 entității în perioada de gestiune \_\_\_\_\_ 71.355 lei.

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

8. Avansurile și creditele acordate membrilor organelor specificate la pct.7 \_\_\_\_\_ lei, inclusiv rambursate \_\_\_\_\_ lei.

9. Valoarea activelor imobilizate și circulante, înregistrate în calitate de gaj<sup>1</sup>

1) valoarea de gaj \_\_\_\_\_ lei,

2) valoarea contabilă \_\_\_\_\_ lei.

10. Numărul acțiunilor ordinare la finele perioadei de gestiune \_\_\_\_\_ unități.

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

1) profit \_\_\_\_\_ lei,

2) pierdere \_\_\_\_\_ lei.

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

1) plătite \_\_\_\_\_ lei,

2) planificate pentru plată \_\_\_\_\_ lei.

13. Valută străină disponibilă, recalculată în monedă națională a Republicii Moldova – total \_\_\_\_\_ lei, inclusiv (lei, denumirea și codul valutei):

) \_\_\_\_\_ codul valutei \_\_\_\_\_

14. Numerar legat – total \_\_\_\_\_ lei.

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

a) la numărător – valoarea de gaj;

b) la numitor – valoarea contabilă

\_\_\_\_\_





**NOTĂ INFORMATIVĂ**  
privind relațiile cu nerezidenții

Tabelul 1

Creanțe, investiții financiare și datorii pe termen lung aferente *fondatorilor* nerezidenți

| Indicatori   | Cod rd./<br>cod țară | Sold la începutul<br>perioadei de<br>gestiune | Modificări în perioada de gestiune |                      |                              | Sold la sfârșitul<br>perioadei de<br>gestiune |
|--|----------------------|---|------------------------------------|----------------------|------------------------------|---|
|  |                      |   | Intrări/<br>majorări               | Ieșiri/<br>diminuări | Diferențe de curs<br>valutar |   |
| 1  | 2                    | 3   | 4                                  | 5                    | 6                            | 7   |
| <b>Creanțe și investiții financiare pe termen lung – total</b>                                   | <b>010</b>           |   |                                    |                      |                              |   |
| Creanțe comerciale, <i>inclusiv pe țări:</i>   | 020                  |   |                                    |                      |                              |   |
| Avansuri acordate, <i>inclusiv pe țări:</i>  | 030                  |   |                                    |                      |                              |   |
| Împrumuturi acordate și creanțe privind leasingul financiar,<br><i>inclusiv pe țări:</i>         | 040                  |   |                                    |                      |                              |   |
| Alte creanțe și investiții financiare, <i>inclusiv pe țări:</i>                                  | 050                  |   |                                    |                      |                              |   |
| <b>Datorii pe termen lung – total</b>  | <b>060</b>           |   |                                    |                      |                              |   |
| Datorii comerciale, <i>inclusiv pe țări:</i>   | 070                  |   |                                    |                      |                              |   |
| Avansuri primite, <i>inclusiv pe țări:</i>   | 080                  |   |                                    |                      |                              |   |
| Credite bancare, împrumuturi și datorii privind leasingul financiar,<br><i>inclusiv pe țări:</i> | 090                  |   |                                    |                      |                              |   |
| Alte datorii, <i>inclusiv pe țări:</i>   | 100                  |   |                                    |                      |                              |   |

Creanțe, investiții financiare și datorii pe termen lung aferente nerezidenților, *cu excepția fondatorilor*

| Indicatori   | Cod rd./<br>cod țară | Sold la începutul<br>perioadei de<br>gestiune | Modificări în perioada de gestiune |                      |                              | Sold la sfârșitul<br>perioadei de<br>gestiune |
|--|----------------------|---|------------------------------------|----------------------|------------------------------|---|
|  |                      |   | Intrări/<br>majorări               | Ieșiri/<br>diminuări | Diferențe de curs<br>valutar |   |
| 1  | 2                    | 3   | 4                                  | 5                    | 6                            | 7   |
| <b>Creanțe și investiții financiare pe termen lung – total</b>                                   | <b>010</b>           |   |                                    |                      |                              |   |
| Creanțe comerciale, <i>inclusiv pe țări:</i>   | 020                  |   |                                    |                      |                              |   |
| Avansuri acordate, <i>inclusiv pe țări:</i>  | 030                  |   |                                    |                      |                              |   |
| Împrumuturi acordate și creanțe privind leasingul financiar,<br><i>inclusiv pe țări:</i>         | 040                  |   |                                    |                      |                              |   |
| Depozite, <i>inclusiv pe țări:</i>   | 050                  |   |                                    |                      |                              |   |
| Alte creanțe și investiții financiare, <i>inclusiv pe țări:</i>                                  | 060                  |   |                                    |                      |                              |   |
| <b>Datorii pe termen lung – total</b>  | <b>070</b>           |   |                                    |                      |                              |   |
| Datorii comerciale, <i>inclusiv pe țări:</i>   | 080                  |   |                                    |                      |                              |   |
| Avansuri primite, <i>inclusiv pe țări:</i>   | 090                  |   |                                    |                      |                              |   |
| Credite bancare, împrumuturi și datorii privind leasingul financiar,<br><i>inclusiv pe țări:</i> | 100                  |   |                                    |                      |                              |   |
| Alte datorii, <i>inclusiv pe țări:</i>   | 110                  |   |                                    |                      |                              |   |







## Investiții financiare în străinătate și participarea nerezidenților în capitalul social

| Indicatori  | Cod rd./<br>cod țară | Sold la începutul<br>perioadei de gestiune | Intrări/<br>majorări | Ieșiri/<br>diminuări | Sold la sfârșitul<br>perioadei de gestiune |
|---|----------------------|--|----------------------|----------------------|--|
| 1   | 2                    | 3  | 4                    | 5                    | 6  |
| <b>Investiții financiare</b>  | 010                  |  |                      |                      |  |
| Cote de participație și acțiuni de până la 10% inclusiv, în capitalul social al entităților nerezidente, <i>inclusiv pe țări:</i> | 020                  |  |                      |                      |  |
| Cote de participație și acțiuni de peste 10% în capitalul social al entităților nerezidente, <i>inclusiv pe țări:</i>             | 030                  |  |                      |                      |  |
| <b>Capital social</b>   | 040                  |  |                      |                      |  |
| Cote de participație și acțiuni de până la 10% inclusiv, <i>inclusiv pe țări:</i>   | 050                  |  |                      |                      |  |
| Cote de participație și acțiuni de peste 10%, <i>inclusiv pe țări:</i>  | 060                  |  |                      |                      |  |

## Bunuri ale nerezidenților înregistrate în conturi extrabilanțiere

| Indicatori  | Cod rd./<br>cod țară | Sold la începutul<br>perioadei de gestiune | Intrări/<br>diminuări | Ieșiri/<br>micșorări | Sold la sfârșitul<br>perioadei de gestiune |
|---|----------------------|--|-----------------------|----------------------|--|
| 1   | 2                    | 3  | 4                     | 5                    | 6  |
| <b>Bunuri primite în baza contractelor de comision, <i>inclusiv pe țări</i></b> | 010                  |  |                       |                      |  |
| Bunuri primite spre prelucrare, <i>inclusiv pe țări</i>                         | 020                  |  |                       |                      |  |
| Bunuri obținute din materialele prelucrate, <i>inclusiv pe țări</i>             | 030                  |  |                       |                      |  |



## Venituri și cheltuieli aferente tranzacțiilor cu nerezidenții

| Indicatori  | Cod rd. | Perioada de gestiune |         |
|---|---------|----------------------|---------|
|   |         | precedentă           | curentă |
| 1   | 2       | 3                    | 4       |
| <b>Venituri – total</b>   | 010     |                      |         |
| Venituri aferente bunurilor procurate și vândute peste hotare fără trecerea frontierei de stat a Republicii Moldova, <i>inclusiv pe țări:</i>   | 020     |                      |         |
| Venituri din dobânzi aferente activității operaționale și altor activități, <i>inclusiv pe țări:</i>  | 030     |                      |         |
| Venituri din dividende și participații în alte entități, <i>inclusiv pe țări:</i>   | 040     |                      |         |
| Venituri din decontarea datoriilor cu termenul de prescripție expirat, <i>inclusiv pe țări:</i>   | 050     |                      |         |
| Alte venituri, <i>inclusiv pe țări:</i>   | 060     |                      |         |
| <b>Cheltuieli – total</b>   | 070     |                      |         |
| Cheltuieli aferente bunurilor procurate și vândute peste hotare fără trecerea frontierei de stat a Republicii Moldova, <i>inclusiv pe țări:</i> | 080     |                      |         |
| Cheltuieli privind dobânzile, <i>inclusiv pe țări:</i>  | 090     |                      |         |
| Cheltuieli și provizioane aferente creanțelor comerciale și altor creanțe compromise, <i>inclusiv pe țări:</i>                                  | 100     |                      |         |
| Alte cheltuieli, <i>inclusiv pe țări:</i>   | 110     |                      |         |

**Persoanele responsabile de semnarea rapoartelor financiare ale entității\***

\* conform art.36 din Legea contabilității



# 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 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 84868

Issued To:

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

| Number  | Device Name   | Intended purpose per IFU |
|---|---|--------------------------|
| <b>Class III products under the scope of CE 84868</b> |   |                          |
| N/A   | Attain Clarity Venogram Balloon Catheter  | See CE 593123            |
| N/A   | Driver Sprint Rapid Exchange Coronary Stent System  | See CE 545439            |
| N/A   | Endeavor Resolute Zotarolimus-Eluting Coronary Stent System<br>Resolute Integrity Zotarolimus-Eluting Coronary Stent System | See CE 514336            |
| N/A   | Endeavor Sprint Zotarolimus-Eluting RX Coronary Stent System  | See CE 86406             |
| N/A   | Endurant™ Stent Graft System<br>Endurant™ II Stent Graft System<br>Endurant™ IIs Stent Graft System                         | See CE 559659            |
| N/A   | Euphora Rapid Exchange Balloon Dilatation Catheter  | See CE 622066            |
| N/A   | Heli-FX™ EndoAnchor™ Systems  | See CE 669930            |
| N/A   | IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)  | See CE 570280            |

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 84868

Issued To:

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

| Number  | Device Name   | Intended purpose per IFU |
|---|---|--------------------------|
| <b>Class III products under the scope of CE 84868</b> |   |                          |
| N/A   | IN.PACT Falcon (Paclitaxel-eluting PTCA Balloon Catheter) | See CE 570282            |
| N/A   | IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter) | See CE 570281            |
| N/A   | Integrity Rapid Exchange Coronary Stent System            | See CE 91271             |
| N/A   | Micra™ Introducer Sheath with Hydrophilic Coating         | See CE 599898            |
| N/A   | NC Euphora Rapid Exchange Balloon Dilatation Catheter     | See CE 612356            |
| N/A   | NC Solarice Rapid Exchange Balloon Dilatation Catheter    | See CE 630635            |
| N/A   | NC Sprinter Rapid Exchange Balloon Dilatation Catheter    | See CE 506473            |
| N/A   | Reliant Stent Graft Balloon Catheter                      | See CE 635936            |
| N/A   | Resolute Onyx Zotarolimus-Eluting Coronary Stent System   | See CE 618060            |
| N/A   | Sentrant Introducer Sheath with Hydrophilic Coating       | See CE 595294            |
| N/A   | Solarice Rapid Exchange Balloon Dilatation Catheter       | See CE 630580            |
| N/A   | Sprinter Legend OTW Balloon Dilatation Catheter           | See CE 547584            |

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 3 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 84868

Issued To:

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

| Number  | Device Name  | Intended purpose per IFU |
|---|--|--------------------------|
| <b>Class III products under the scope of CE 84868</b> |  |                          |
| N/A   | Sprinter Legend RX Balloon Dilatation Catheter                 | See CE 525652            |
| N/A   | Sprinter Over-the-Wire Balloon Dilatation Catheter             | See CE 92065             |
| N/A   | Telescope Guide Extension Catheter                             | See CE 701802            |
| N/A   | Valiant Navion™ Thoracic Stent Graft System                    | See CE 702496            |
| N/A   | Valiant Thoracic Stent Graft with the Captivia Delivery System | See CE 554030            |

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 4 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 84868

Issued To:

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

| Class IIb products under the scope of CE 84868 |   |   |
|--|---|---|
| GMDN #   | Device or Generic Device Group  | Intended Purpose per IFU  |
| 58893<br>(Catheter)<br>35156<br>(Generator)    | Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter & Symlicity G3™ Renal Denervation RF Generator | The Symlicity G3™ Renal Denervation RF Generator when used with the Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter is intended to deliver low-level radio frequency (RF) energy through the wall of the renal artery to denervate the human kidney. |

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 5 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 84868

Issued To:

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

| Class IIb products under the scope of CE 84868 |                                    |  |
|--|------------------------------------|--|
| GMDN #   | Device or Generic Device Group     | Intended Purpose per IFU   |
| 46777  | Talent Endoluminal Occluder System | The Talent Endoluminal Occluder System is intended for endoluminal occlusion of the contralateral iliac artery in cases where an abdominal aortic aneurysm is treated with an aorto-uni-iliac stent graft and subsequent femoral-to-femoral bypass procedure |

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 6 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 84868

Issued To:

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

| Class IIa products under the scope of CE 84868 |                                |   |
|--|--------------------------------|---|
| NBOG code                                      | Device or Generic Device Group | Intended Purpose per IFU  |
| MD0106   | Confida™ Expandable Sheath     | The Confida™ Expandable Sheath is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters or devices introduced into the femoral iliac arteries. |

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 7 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# 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: **2019-08-22**  
 Issued To: **Medtronic, Inc.**  
**710 Medtronic Parkway**  
**Minneapolis, MN 55432**  
**USA**

| <b>Subcontractor:</b>   | <b>Service(s) supplied</b> |
|---|----------------------------|
| Invatec S.p.A.<br>Via Martiri della Libertà 7<br>25030 Roncadelle (BS)<br>Italy       | <b>Manufacture</b>         |
| Medistri SA<br>Rte de L'Industrie 96<br>1564 Domdidier<br>Switzerland                 | <b>ETO Sterilization</b>   |
| Medtronic B.V. / E.O.C.<br>Earl Bakkenstraat 10<br>6422 PJ Heerlen<br>The Netherlands | <b>EU Representative</b>   |
| Medtronic CoreValve LLC<br>1851 E. Deere Ave<br>Santa Ana, CA 92705<br>USA            | <b>Manufacture</b>         |

...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 84868**  
 Date: **2019-08-22**  
 Issued To: **Medtronic, Inc.**  
**710 Medtronic Parkway**  
**Minneapolis, MN 55432**  
**USA**

| <b>Subcontractor:</b>   | <b>Service(s) supplied</b>                                      |
|---|---|
| Medtronic Ireland<br>Parkmore Business Park West<br>Galway<br>Ireland   | <b>Design</b><br><b>EU Representative</b><br><b>Manufacture</b> |
| Medtronic Mexico EG<br>Carret. Int. Km. 1969<br>Guad-Nogales Km. 2<br>85340 Empalme<br>Sonora<br>Mexico               | <b>Manufacture</b>  |
| Medtronic Mexico S. de R.L. de CV<br>Av. Paseo Cucapah 10510 El Lago<br>C.P. 22210 Tijuana, Baja California<br>Mexico | <b>Manufacture</b>  |
| Medtronic Vascular<br>3576 Unocal Place<br>Santa Rosa<br>California 95403<br>USA                                      | <b>Design</b>   |

...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 84868**  
Date: **2019-08-22**  
Issued To: **Medtronic, Inc.**  
**710 Medtronic Parkway**  
**Minneapolis, MN 55432**  
**USA**

| <b>Subcontractor:</b>   | <b>Service(s) supplied</b> |
|---|----------------------------|
| Phoenix DeVentures, Inc.<br>18655 Madrone Parkway<br>Suite 180<br>Morgan Hill<br>California<br>95037<br>USA             | <b>Manufacture</b>         |
| Plexus Corp.<br>Pinnacle Hill<br>Kelso<br>TD5 8XX<br>United Kingdom   | <b>Manufacture</b>         |
| Plexus Manufacturing Sdn. Bhd.<br>Bayan Lepas Free Industrial Zone<br>Phase II, 11900 Bayan Lepas<br>Penang<br>Malaysia | <b>Manufacture</b>         |

...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 84868**  
 Date: **2019-08-22**  
 Issued To: **Medtronic, Inc.**  
**710 Medtronic Parkway**  
**Minneapolis, MN 55432**  
**USA**

| <b>Subcontractor:</b>   | <b>Service(s) supplied</b> |
|---|----------------------------|
| SSP-SiMatrix, Inc.<br>1131 North US Highway 93<br>Victor<br>Montana<br>59875<br>USA     | <b>Manufacture</b>         |
| Sterigenics US, LLC<br>4900 Gifford Avenue<br>Los Angeles<br>California<br>90058<br>USA | <b>ETO Sterilization</b>   |
| Surmodics, Inc.<br>9924 West 74th Street<br>Eden Prairie<br>Minnesota<br>55344<br>USA   | <b>Crucial Supplier</b>    |

...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 84868**  
 Date: **2019-08-22**  
 Issued To: **Medtronic, Inc.**  
**710 Medtronic Parkway**  
**Minneapolis, MN 55432**  
**USA**

| <b>Subcontractor:</b>  | <b>Service(s) supplied</b>                              |
|--|---|
| Synergy Health Ireland Ltd<br>(Synergy Health - AST - Ireland)<br>IDA Business & Technology Park<br>Tullamore, Co. Offaly<br>Ireland                                   | <b>E Beam Sterilization</b><br><b>ETO Sterilization</b> |
| Synergy Health Sterilisation UK Ltd<br>(Synergy Health - AST - Daventry)<br>Brunel Close<br>Drayton Fields Industrial Estate<br>Daventry<br>NN11 8RB<br>United Kingdom | <b>E Beam Sterilization</b>                             |
| Teleflex Medical<br>Annacotty Business Park<br>Annacotty<br>Co. Limerick<br>Ireland  | <b>Manufacture</b>                                      |

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**  
 Date: **2019-08-22**  
 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:-<br><br>Q252.322, Q252.407, Q252.426, Q252.427, Q252.428, Q252.467, Q252.480, Q252.587, and Q252.611<br><br>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 |                  | PTCA 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.   |

...making excellence a habit.™

Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
 This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 84868**  
 Date: **2019-08-22**  
 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.<br>Addition of the activity of EU Representative for Medtronic Ireland.   |
| 13 August 2009  | 7432878          | Certificate renewal.<br>Addition of Accellant Inc as a manufacturing subcontractor, amendment to company name for Isotron PLC, Daventry, and Steris Corporation, Sandy, Utah.<br>Change to address for the subcontractor, Nutek Corporation.<br>Addition of E Beam Sterilization for Isotron Ireland.<br>Rewording of scope for clarification purposes only. |
| 29 July 2010    | 7546410          | Added C.R. Bard, Inc. to the list of significant subcontractors for manufacturing.<br>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: **2019-08-22**  
 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 19 <sup>th</sup> December 2012 on the certificate history page. |



# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 84868**  
 Date: **2019-08-22**  
 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.  |
| 01 May 2018     | 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'. |
| 06 March 2019   | 8786554          | Traceable to NB 0086.   |



# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**  
 Date: **2019-08-22**  
 Issued To: **Medtronic, Inc.**  
**710 Medtronic Parkway**  
**Minneapolis, MN 55432**  
**USA**

| Date    | Reference Number | Action  |
|---------|------------------|---|
| Current | 9736517          | <p>Certificate Renewal.</p> <p>Added product table per MDP4500 Appendix A.</p> <p>Clarified addresses of subcontractors to exactly align with their ISO certificate name and address.</p> <p>Remove "sterile Iliac Stents and Delivery Systems, sterile Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems" from scope as the Complete SE product (iliac and vascular indications) is no longer manufactured nor in the distribution chain.</p> <p>Remove Assurant Cobalt product (iliac product scope) it is no longer manufactured and the last product builds expired in April 2019.</p> <p>Remove subcontractors – Admedes Schuessler GmbH, Germany, Flextronics Medical, Austria, Sterigenics, Corona, CA, Synergy Health, Ireland related to removed products above.</p> <p>Add subcontractors - Phoenix DeVentures, CA, Sterigenics, Los Angeles, CA, SurModics, MN and Medtronic, Santa Ana, CA related to new Class IIa product Confida Expandable Sheath.</p> |

# CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands

including the implementation meets the requirements of the standard:

# EN ISO 13485:2016 ISO 9001:2015

### Scope:

Sales, order management, warehousing and distribution of medical devices.  
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021  
Certificate effective date: 1 July 2018  
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Certified organization(s) and/or locations:

|   |   |
|---|---|
|   | Different scope   |
| Medtronic Portugal LDA-<br>Rua Tomas da Fonseca Torre E, 11<br>piso<br>1600 Lisboa<br>Portugal  | Sales, Order Management and distribution of medical devices including technical service and customer education.<br><br>Warehousing and distribution of medical devices, including spine loaner operations |
| Medtronic Italia S.p.A.<br>Via Varesina 162<br>20156 Milano<br>Italy  | Sales, order management and distribution of medical devices. Including technical service and customer education. Promotion, invoice and order management of medicinal products.                           |
| Medtronic Danmark A/S.<br>Arne Jacobsens Allé 17<br>2300 Kopenhagen<br>Denmark  | Sales, order management and distribution of medical devices. Including technical service and customer education   |
| Medtronic Medikal Teknoloji Ticaret Ltd<br>Sti<br>Saray Mah. Esnaf Sk.<br>Akkom Ofis Park Laodik Plaza<br>Sitesi B Blok Apt: 2/8<br>00000 Umraniye - Istanbul<br>Turkey | Sales, order management and distribution of medical devices. Including technical service and customer education   |



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.  
Waterfall Distribution Campus  
CNR K101 and Bridal Veil Road  
Waterfall Midrand  
1685 Gauteng  
South Africa

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Ibérica S.A.  
Calle de María de Portugal, 11  
28050 Madrid  
Spain

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Romania SRL  
Ploiesti 42-44, Building B, B2  
Wing, 2nd floor, district 1  
Baneasa Business & Technology Park  
013696 Bucharest  
Romania

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Norge AS  
Martin Linges vei 25  
1364 Fornebu  
Norway

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Portugal, LDA-  
Avenida Gomes Pereira 61B  
Benfica  
1600 Lisboa  
Portugal

Sales, Order Management and distribution of medical devices Including technical service and customer education.

Warehousing and distribution of medical devices, including spine loaner operations.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Service & Repair CoE  
C-Mill gebouw K  
Jan Campertstraat 21-A  
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.  
Polígono Industrial La Garena  
Calle Francisco Rabal 7  
28806 Alcalá De Heneras, Madrid  
Spain

Spine loaner operations.

Medtronic Ibérica S.A.  
WTC Almeda Park  
Placa de la Pau, s/n. Edificio 7, 3 piso  
08940 Cornellà de Llobregat, Barcelona  
Spain

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS  
27/33 Quai Alphonse Le Gallo  
92513 Boulogne-Billancourt  
France

Sales, order management and distribution of medical devices. Including technical Service and customer education

Medtronic Trading NL B.V.  
Larixplein 4  
5616 VB Eindhoven

Sales, order management and distribution of medical devices. Including technical service and customer education

Medtronic GmbH  
Earl-Bakken-Platz 1  
40670 Meerbusch  
Germany

Distribution of medical Devices, medical equipment and related services.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Osterreich GmbH  
Millennium Tower, 20th floor  
Handelskai 94-96  
1200 Wien  
Austria

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic (Schweiz) AG  
Talstrasse 9  
3053 Munchenbuchsee  
Switzerland

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic Hellas S.A.  
Avenue Kifisias 24 Building B  
151 25 Marousi Pref. Attica  
Greece

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Serbia Ltd.  
Bulevar Zorana Djindjica, 64a  
11070 Belgrade  
Serbia

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.  
Bocskai út 134-146  
Cépulet 3. emelet  
1113 Budapest  
Hungary

Sales, order management and distribution of medical devices. Including customer education.

Medtronic CCO SSC Warsaw  
Polna 11  
00-633 Warszawa  
Poland

Order management of medical devices.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Finland Oy  
Lentäjätie 3  
01530 Vantaa  
Finland

Sales, order management and distribution of medical devices.  
Including technical service and customer education.

Medtronic AB  
P.O. Box 1034  
164 21 Kista  
Sweden

Sales, order management and distribution of medical devices.  
Including technical service and customer education

Medtronic Trading Ltd.  
10 Hamada Street  
4673344 Herzlyia  
Israel

Import, sales, order management and distribution of medical  
devices. Including technical service and customer education

Addendum expiry date: 1 July 2021  
Addendum effective date: 1 July 2018



# CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands

including the implementation meets the requirements of the standard:

# EN ISO 13485:2016 ISO 9001:2015

### Scope:

Sales, order management, warehousing and distribution of medical devices.  
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021  
Certificate effective date: 1 July 2018  
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Certified organization(s) and/or locations:

|   |   |
|---|---|
|   | Different scope   |
| Medtronic Portugal LDA-<br>Rua Tomas da Fonseca Torre E, 11<br>piso<br>1600 Lisboa<br>Portugal  | Sales, Order Management and distribution of medical devices including technical service and customer education.<br><br>Warehousing and distribution of medical devices, including spine loaner operations |
| Medtronic Italia S.p.A.<br>Via Varesina 162<br>20156 Milano<br>Italy  | Sales, order management and distribution of medical devices. Including technical service and customer education.<br>Promotion, invoice and order management of medicinal products.                        |
| Medtronic Danmark A/S.<br>Arne Jacobsens Allé 17<br>2300 Kopenhagen<br>Denmark  | Sales, order management and distribution of medical devices. Including technical service and customer education   |
| Medtronic Medikal Teknoloji Ticaret Ltd<br>Sti<br>Saray Mah. Esnaf Sk.<br>Akkom Ofis Park Laodik Plaza<br>Sitesi B Blok Apt: 2/8<br>00000 Umraniye - Istanbul<br>Turkey | Sales, order management and distribution of medical devices. Including technical service and customer education   |



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.  
Waterfall Distribution Campus  
CNR K101 and Bridal Veil Road  
Waterfall Midrand  
1685 Gauteng  
South Africa

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Ibérica S.A.  
Calle de María de Portugal, 11  
28050 Madrid  
Spain

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Romania SRL  
Ploiesti 42-44, Building B, B2  
Wing, 2nd floor, district 1  
Baneasa Business & Technology Park  
013696 Bucharest  
Romania

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Norge AS  
Martin Linges vei 25  
1364 Fornebu  
Norway

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Portugal, LDA-  
Avenida Gomes Pereira 61B  
Benfica  
1600 Lisboa  
Portugal

Sales, Order Management and distribution of medical devices Including technical service and customer education.

Warehousing and distribution of medical devices, including spine loaner operations.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Service & Repair CoE  
C-Mill gebouw K  
Jan Campertstraat 21-A  
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.  
Polígono Industrial La Garena  
Calle Francisco Rabal 7  
28806 Alcalá De Heneras, Madrid  
Spain

Spine loaner operations.

Medtronic Ibérica S.A.  
WTC Almeda Park  
Placa de la Pau, s/n. Edificio 7, 3 piso  
08940 Cornellà de Llobregat, Barcelona  
Spain

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS  
27/33 Quai Alphonse Le Gallo  
92513 Boulogne-Billancourt  
France

Sales, order management and distribution of medical devices. Including technical Service and customer education

Medtronic Trading NL B.V.  
Larixplein 4  
5616 VB Eindhoven

Sales, order management and distribution of medical devices. Including technical service and customer education

Medtronic GmbH  
Earl-Bakken-Platz 1  
40670 Meerbusch  
Germany

Distribution of medical Devices, medical equipment and related services.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Osterreich GmbH  
Millennium Tower, 20th floor  
Handelskai 94-96  
1200 Wien  
Austria

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic (Schweiz) AG  
Talstrasse 9  
3053 Munchenbuchsee  
Switzerland

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic Hellas S.A.  
Avenue Kifisias 24 Building B  
151 25 Marousi Pref. Attica  
Greece

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Serbia Ltd.  
Bulevar Zorana Djindjica, 64a  
11070 Belgrade  
Serbia

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.  
Bocskai út 134-146  
Cépulet 3. emelet  
1113 Budapest  
Hungary

Sales, order management and distribution of medical devices. Including customer education.

Medtronic CCO SSC Warsaw  
Polna 11  
00-633 Warszawa  
Poland

Order management of medical devices.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Finland Oy  
Lentäjätie 3  
01530 Vantaa  
Finland

Sales, order management and distribution of medical devices.  
Including technical service and customer education.

Medtronic AB  
P.O. Box 1034  
164 21 Kista  
Sweden

Sales, order management and distribution of medical devices.  
Including technical service and customer education

Medtronic Trading Ltd.  
10 Hamada Street  
4673344 Herzlyia  
Israel

Import, sales, order management and distribution of medical  
devices. Including technical service and customer education

Addendum expiry date: 1 July 2021  
Addendum effective date: 1 July 2018