

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 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Subcontractor:	Service(s) supplied
Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica	Design Manufacture
Boston Scientific Corporation 4100 Hamline Avenue North St. Paul MN 55112-5798 USA	Design Manufacture
Boston Scientific Corporation 780 Brookside Drive Spencer Indiana 47460 USA	Manufacture

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Subcontractor:	Service(s) supplied
Boston Scientific Corporation Two Scimed Place Maple Grove Minnesota 55311 USA	Design Manufacture
Boston Scientific Limited Ballybrit Business Park Galway Ireland	EU Representative Manufacture
Boston Scientific Limited Business and Technology Park Model Farm Road Cork Ireland	Manufacture

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Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland	Labelling Manufacture
Boston Scientific Medical Device (Malaysia) SDN BHD PMT 741, Persiaran Cassia Selatan 1 Taman Perindustrian Batu Kawan 14110 Bandar Cassia Pulau Pinang Malaysia	Manufacture

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Subcontractor:	Service(s) supplied
Boston Scientific Technology & Engineering Services Pvt., Ltd. 3rd Floor, Bestech Business Tower Sector 48 Sohna Road Gurgaon Haryana 122018 India	Design
BSC Coventry 8 Industrial Drive Coventry Rhode Island 02816 USA	ETO Sterilization

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Creation Technologies LP 8977-8999 Fraserton Court Burnaby British Columbia V5J 5H8 Canada	Manufacture
EirMed 5120 Eagle Point Road Menomonie WI 54751 USA	Manufacture
Electron Beam SDN. BHD. Lot 7 Jalan Sungai Pinang 4/3 Taman Perindustrian Pulau Indah (FASA 2) 42920 Port Klang Selangor Malaysia	E Beam Sterilization

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FMD. Co., Ltd. 1-166 Shimo-obari-nakashima Komaki-shi Aichi 485-0051 Japan	Design Manufacture
Goals Sterilization Co., Ltd. East of Renkangtang South of 07 provincial road, Xinfeng Town Nanhu District 314005 Jiaxing, Zhejiang China	ETO Sterilization
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	Gamma Sterilization

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Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
Isomedix Operations, Inc. 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	ETO Sterilization
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	ETO Sterilization

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Jiangsu JianYu Health Medical Co., Ltd. Zhixi Town Industry Zone Jintan City, Jiangsu Province 213251 China	Manufacture
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Control of Sterilization Manufacture
Lake Region Medical Limited Butlersland New Ross Co. Wexford Ireland	Manufacture

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Subcontractor:	Service(s) supplied
Lake Region Medical Sdn. Bhd 91- B Lebuhraya Kampung Jawa 11900 Bayan Lepas Penang Malaysia	Manufacture
Light Guide Optics International Celtniecibas iela 8 Livani LV-5316 Latvia	Manufacture Packaging
Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern PA 19355 USA	Manufacture

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Subcontractor:	Service(s) supplied
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	Manufacture Testing
Navilyst Medical, Inc. 10 Glens Falls Technical Park Glens Falls NY 12801 USA	Manufacture
Northern Digital, Inc. (NDI) 103 Randall Drive Waterloo Ontario N2V 1C5 Canada	Manufacture

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Subcontractor:	Service(s) supplied
Statice Z.I des Tilleroyes 9 rue Thomas Edison 25000 Besancon France	Manufacture
Stellartech Research Corporation 560 Cottonwood Drive Milpitas California 95035 USA	Manufacture
Sterigenics 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Gamma Sterilization

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Sterigenics U.S. Inc. 7775 South Quincy Street Willowbrook Illinois 60527 USA	ETO Sterilization
SurModics, Inc 9924 W. 74th Street Eden Prairie Minnesota 55344-3523 USA	Manufacture
Synergy Health Americas 500 West 4th Street Lima Ohio 45804 USA	E Beam Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health AST 9020 Activity Road, Suite D San Diego California 92126 USA	E Beam Sterilization
Synergy Health AST SRL B13.1 Street 4, Avenue 1 El Coyoil Free Zone 20102 El Coyoil Alajuela Costa Rica	ETO Sterilization
Synergy Health AST, SRL B16 Street 4; Avenue O El Coyoil Free Zone El Coyoil Alajuela 20102 Costa Rica	E Beam Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore Co. Offaly Ireland	ETO Sterilization Gamma Irradiation
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	Gamma Sterilization
TechDevice Costa Rica Limitada 400m East Holcim, Zona Industrial FlexiPark, Bodega G6 San Rafael Costa Rica	Manufacture

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Subcontractor:	Service(s) supplied
Teleflex Medical Unit 7, 8, & 9 Annacotty Business Park Annacotty Limerick Ireland	Manufacture
Venusa de Mexico S. de R.L. de C.V. a Lake Region Medical Company Calle Hertz 1525 Parque Industrial Antonio J. Bermudez Chihuahua 32470 Ciudad Juarez Mexico	Manufacture

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EB sertifikatas – visiška kokybės užtikrinimo sistema

Direktyva 93/42/EEB dėl medicinos prietaisų, II priedas, išskyrus 4 skirsnį

Nr.

CE 616288

Išduota (kam):

**Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Masačiusetsas
01752
JAV**

Dėl:

Žr. sertifikato taikymo lapą.

remiantis kokybės užtikrinimo sistemos patikrinimu pagal Tarybos direktyvos 93/42/EEB II priedo reikalavimus, išskyrus 4 skirsnį. Kokybės užtikrinimo sistema atitinka direktyvos reikalavimus. Norint pateikti į rinką III klasės produktus, reikalingas II priedo 4 skirsnio sertifikatas.

„BSI“ vardu minėtos direktyvos notifikuotoji įstaiga (notifikuotosios įstaigos numeris 2797):

/parašas/

Gary E Slack, vyresnysis viceprezidentas, Medicinos prietaisai

Išduota pirmą kartą: **2014-06-30**

Data: **2019-10-02**

Galioja iki: **2021-09-25**

...meistriškumą paverčiame įpročiu
Puslapis 1 iš 2

Šio sertifikato galiojimas priklauso nuo to, ar kokybės sistema bus palaikoma atsižvelgiant į direktyvos reikalavimus, o tai bus įrodoma atliekant būtinus notifikuotosios įstaigos priežiūros veiksmus. Šis patvirtinimas netaikomas visiems produktams, kuriuos suprojektavo ir (arba) pagamino trečioji šalis bendrovės, nurodytos šiame sertifikate, vardu, išskyrus atvejus, kai specialiai sutarta su „BSI“.

Šis sertifikatas išduotas elektroniniu būdu ir yra saistomas sutarties sąlygų.

Informacija ir kontaktai: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdamas, Nyderlandai Tel. Nr.: + 31 20 346 0780 „BSI“ grupė Nyderlandai B.V. Registruota Nyderlanduose pagal Nr. 33264284.
„BSI“ bendrovių grupės narys.

Sertifikato Nr.: CE 616288

Sertifikato taikymo sritis:

Ištūmimo įtaisų, angiografinių kateterių, mikrokateterių, ištūmimo kateterių, radijo dažnio abliacijos kateterių, medicininių lazerių sistemų ir vienkartinį bei daugkartinio naudojimo skaidulinių optinių lazerių tiekimo prietaisų, diagnostinio planavimo, širdies ritmo nustatymo ir matavimo kateterių, planavimo sistemų, elektrochirurginių elektrodų ir generatorių, įrašymo ir stiprintuvo sistemų, įskaitant programinę įrangą, perkutaninių kateterių, stentų, adatų, plečiamųjų medžiagų, priedų, įvadinių kateterių, drenažinių ir urologinių kateterių, urologinio drėkinimo, chirurginių tinklelių, tulžies prietaisų, biopsijos prietaisų, šalinimo prietaisų, nefrostomijos prietaisų, maitinimo prietaisų, ligatorių, polipektomijos prietaisų, hemostazės prietaisų, sfinkterių, siuvimo prietaisų, endoskopų, endoskopinių drenažinių stentų, tiekimo sistemų ir endoskopinės prieigos prietaisų, endoskopinio drėkinimo, endoskopinių kanalų palaikymo rinkinių, endoterapijos elektrodų sistemų, prieširdžių apendiksų uždarymo sistemų ir sterilumo sistemų bei minimaliai invazinių audinių ir trombu šalinimo prietaisų projektavimas, kūrimas ir gamyba.

Varpos protezų su antibakteriniu gydymu ar be jo bei susijusių priedų, sulaikymą skatinančių implantų su antibakteriniu gydymu ar be jo, susijusių priedų ir sterilių chirurginių įrankių projektavimas, kūrimas, gamyba ir sterilizavimas.

Tie II priedo aspektai, kurie susiję su sterilumo užtikrinimu ir palaikymu gaminant „ACUITY LDS“ priedus, kaniules, skysčių administravimo prietaisus, ištraukiamuosius prietaisus, jungiamuosius kabelius ir priedus, šalinimo prietaisus, endoskopinius vožtuvus, endoskopinių kanalų palaikymo rinkinius, biopsijos prietaisus. Tie II priedo aspektai, kurie susiję su pripučiamųjų prietaisų ir priedų metrologinės funkcijos palaikymu.

Išduota pirmą kartą: **2014-06-30**Data: **2019-10-02**Galioja iki: **2021-09-25**...meistriškumą paverčiame įpročiu
Puslapis 2 iš 2

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Informacija ir kontaktai: BSI, 389, Market Street, London W1P 8LP, Anglija
0780 „BSI“ grupė Nyderlandai B.V. Registruota Nyderlanduose pagal Nr. 33264284.
„BSI“ bendrovių grupės narys.

EB sertifikatas – visiška kokybės užtikrinimo sistema

Direktyva 93/42/EEB dėl medicinos prietaisų, II priedas, išskyrus 4 skirsnį

Svarbių subrangovų sąrašas

Pripažintų dalyvaujant teikiant paslaugas, susijusias su produktu, kuriam taikomas:

Sertifikato Nr.: **CE 616288**
Data: **2019-10-02**
Išduota (kam): **Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Masačiusetsas
01752
JAV**

Subrangovas:	Teikiama (-os) paslauga (-os)
Availmed S.A. de C.V. C. Industrial Lt. 001 Mz. 105 No 20905 Int. A Col Cd. Industrial Tichuana Žemutinė Kalifornija Pašto kodas 22444 Meksika	Gamyba
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior B1,C1, E1, E2, F2, G1 (Local A, B, C, G, H) La Mesa Tichuana Pašto kodas 22116 Meksika	Gamyba
Bard Glens Falls Operation 289 Bay Road Queensbury Niujorkas 12804 JAV	Gamyba

...meistriškumą paverčiame įpročiu
Puslapis 1 iš 18

EB sertifikatas – visiška kokybės užtikrinimo sistema

Direktyva 93/42/EEB dėl medicinos prietaisų, II priedas, išskyrus 4 skirsnį

Svarbių subrangovų sąrašas

Pripažintų dalyvaujant teikiant paslaugas, susijusias su produktu, kuriam taikomas:

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Data: **2019-10-02**
Išduota (kam): **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Masačiusetsas
01752
JAV

Subrangovas:	Teikiama (-os) paslauga (-os)
Biomerics, LLC 6030 W Harold Gatty Drive Solt Leik Sitis UT 84116 JAV	Gamyba
Boston Scientific Corporation 100 Boston Scientific Way Marlborough MA 01752 JAV	Projektavimas
Boston Scientific Corporation 125 Cambridgepark Drive Kembridžas MA 02140 JAV	Projektavimas

...meistriškumą paverčiame įpročiu
Puslapis 2 iš 18

EB sertifikatas – visiška kokybės užtikrinimo sistema

Direktyva 93/42/EEB dėl medicinos prietaisų, II priedas, išskyrus 4 skirsnį

Svarbių subrangovų sąrašas

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300 Boston Scientific Way
Marlborough
Masačiusetas
01752
JAV

Subrangovas:	Teikiama (-os) paslauga (-os)
Boston Scientific Corporation 150 Baytech Drive San Chozė CA 95134 USA	Etiketės Gamyba Pakavimas
Boston Scientific Corporation 10700 Bren Road W Minnetonka MN 55343 JAV	Projektavimas Plėtojimas Gamyba
Boston Scientific Corporation 2546 First Street Propark, El Coyal, Alachuella Kosta Rika	Gamyba

...meistriškumą paverčiame įpročiu

Puslapis 3 iš 18