



EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2 Section 4

No. CE 620231
Issued To: **Cardiac Pacemakers, Incorporated,**
a wholly owned subsidiary of Guidant
Corporation, a wholly owned subsidiary
of Boston Scientific Corporation
4100 Hamline Avenue North
St Paul
Minnesota
55112-5798
USA

In respect of:

Implantable Bradycardia Pacemakers:
ESSENTIO MRI, PROPONENT MRI and ACCOLADE MRI Families
ALTRUA 2, ESSENTIO, PROPONENT and ACCOLADE Families
Implantable Cardiac Resynchronization Therapy Pacemakers:
VALITUDE, VALITUDE X4, VISIONIST and VISIONIST X4

BSI has performed a design examination on the above devices in accordance with the Council Directive 90/385/EEC, Annex 2 Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex 2 excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **26 September 2014**

Date: **26 September 2014**

Expiry Date: **25 September 2019**

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Page 1 of 3

EC Design-Examination Certificate

Supplementary Information to CE 620231

Issued To:

**Cardiac Pacemakers, Incorporated,
a wholly owned subsidiary of Guidant
Corporation, a wholly owned subsidiary
of Boston Scientific Corporation
4100 Hamline Avenue North
St Paul
Minnesota
55112-5798
USA**

Model Name	Model Number
ESSENTIO MRI	L110, L111, L131
PROPONENT MRI	L210, L211, L231
ACCOLADE MRI	L310, L311, L331
ALTRUA 2	S701, S702, S722
ESSENTIO	L100, L101, L121
PROPONENT	L200, L201, L209, L221
ACCOLADE	L300, L301, L321
VALITUDE	U125
VALITUDE X4	U128
VISIONIST	U225, U226
VISIONIST X4	U228
Application Software	2869

First Issued: **26 September 2014**

Date: **26 September 2014**

Expiry Date: **25 September 2019**

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EC Design-Examination Certificate

Supplementary Information to CE 620231

Issued To:

**Cardiac Pacemakers, Incorporated,
a wholly owned subsidiary of Guidant
Corporation, a wholly owned subsidiary
of Boston Scientific Corporation
4100 Hamline Avenue North
St Paul
Minnesota
55112-5798
USA**

Certificate History

Date	Reference Number	Action
26 September 2014	10150309	First issue, including Model 2869, v2.01.

First Issued: **26 September 2014**

Date: **26 September 2014**

Expiry Date: **25 September 2019**

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Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798
USA

DECLARATION OF CONFORMITY

Manufacturer

Cardiac Pacemakers Incorporated
a wholly owned subsidiary of Guidant Corporation,
a wholly owned subsidiary of Boston Scientific Corporation
4100 Hamline Avenue North,
St. Paul, Minnesota 55112-5798
USA

Manufacturing Site

Boston Scientific Clonmel Limited
Cashel Road,
Clonmel, Co. Tipperary, Ireland

EU Authorized Representative

Guidant Europe NV/SA
Green Square; Lambroekstraat 5D,
1831 Diegem Belgium

Products

Model Name	Model Number
ESSENTIO MRI	L110, L111, L131
PROPONENT MRI	L210, L211, L231
ACCOLADE MRI	L310, L311, L331
ALTRUA 2	S701, S702, S722
ESSENTIO	L100, L101, L121
PROPONENT	L200, L201, L209, L221
ACCOLADE	L300, L301, L321
VALITUDE CRT-P	U125
VALITUDE X4 CRT-P	U128
VISIONIST CRT-P	U225, U226
VISIONIST X4 CRT-P	U228
Application Software	2869 v2.01

Applicable Directive

Active Implantable Medical Devices Directive (90/385/EEC)

Device Classification

Active Implantable Medical Device

Route to Conformity

Council Directive 90/385/EEC (AIMDD) Annex 2 Section 4 Examination of the Design of the Product

Original Issue: Ingenio 2 and ImageReady™ MR Conditional Pacing System

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798
USA

Design Examination Certificate

Certificate Number: CE 620231 Design Examination
Issued By: The British Standards Institution (BSI) (Notified Body # 0086)
Expiration Date: 25 September 2019

Quality Management System Certificate

Certificate Number: FM 71197 QMS - ISO 13485:2003
Registrar: The British Standards Institution (BSI)

Full Quality Assurance Certificate

Certificate Number: CE 00027 Full Quality Assurance
Issued By: The British Standards Institution (BSI) (Notified Body # 0086)

Declaration of Conformity

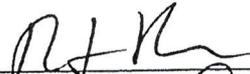
I hereby declare that the above mentioned devices comply with the Essential Requirements and Provisions of the Active Implantable Medical Devices Directive 90/385/EEC

Authorized Signatory

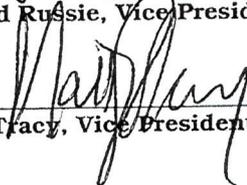
Date 26 September 2014



Kristen Harty, Director Regulatory Affairs



Renold Rusie, Vice President Quality Assurance



Matt Tracy, Vice President Program Management

EB projekto patikros sertifikatas

Direktyva 90/385 / EEB dėl aktyviųjų implantuojamųjų medicinos prietaisų, 2 priedas 4 skirsnis

Nr.
Kam išduota:

CE 620231
Implantuojami širdies stimulatoriai,
Guidant Corporation bendrovei visiškai
priklausanti dukterinė įmonė
Boston Scientific Corporation bendrovei visiškai
priklausanti dukterinė įmonė
4100 Hamline Avenue North
St. Paul
Minnesota
55112-5798
JAV

Dėl:

Bardikardijos gydymui skirtų implantuojamų širdies ritmo stimuliatorių:
ESSENTIO MRI, PROPONENT MRI ir ACCOLADE MRI grupės
ALTRUA 2, ESSENTIO, PROPONENT ir ACCOLADE grupės
Implantuojamųjų širdies resinchronizacinės terapijos kardiostimuliatorių:
VALITUDE, VALITUDE X4, VISIONIST ir VISIONIST X4

BSI atliko anksčiau minėtų prietaisų projekto patikrą pagal Tarybos direktyvos 90/385/EEB, 2 priedo 4 skirsnio nuostatas. Projektas atitinka šios direktyvos reikalavimus. Šių produktų prekybai reikalingas papildomas sertifikatas pagal 2 priedą, išskyrus 4 skirsnį.

BSI vardu ir pavedimu paskelbtoji (notifikuotoji) įstaiga minėtos direktyvos pagrindu (paskelbtosios įstaigos numeris 0086):

/parašas/ _____
Gary Fenton, bendrosios kokybės užtikrinimo direktorius

Pirmojo išdavimo data: 2014 m. rugsėjo mėn. 26 d.

Data: 2014 m. rugsėjo mėn. 26 d.

Galioja iki: 2019 m. rugsėjo mėn. 25 d.

...kompetenciją paverčiame įpročiu™

Psl. 1 iš 3

Šis sertifikatas galioja tik tuo atveju, jei palaikomos kokybės sistemos sąlygos, atitinkančios direktyvos reikalavimus, kaip nurodo notifikuotoji įstaiga, atlikdama priežiūros veiklą.

Šis sertifikatas išduotas elektroniniu būdu ir yra susietas su sutarties sąlygomis.

EB projekto patikros sertifikatas

Papildoma informacija dėl CE 620231

Kam išduota:

**Implantuojami širdies stimulatoriai,
Guidant Corporation bendrovei visiškai
priklausanti dukterinė įmonė
Boston Scientific Corporation bendrovei visiškai
priklausanti dukterinė įmonė
4100 Hamline Avenue North
St. Paul
Minesota
55112-5798
JAV**

Modelio pavadinimas	Modelio Nr.
ESSENTIO MRI	L110, L111, L131
PROPONENT MRI	L210, L211, L231
ACCOLADE MRI	L310, L311, L331
ALTRUA 2	S701, S702, S722
ESSENTIO	L100, L101, L121
PROPONENT	L200, L201, L209, L221
ACCOLADE	L300, L301, L321
VALITUDE	U125
VALITUDE X4	U128
VISION IST	U225, U226
VISIONIST X4	U228
Taikomoji programinė įranga	2869

Pirmojo išdavimo data: 2014 m. rugsėjo mėn. 26 d.

Data: 2014 m. rugsėjo mėn. 26 d.

Galioja iki: 2019 m. rugsėjo mėn. 25 d.

...kompetenciją paverčiame įpročiu™

Psl. 2 iš 3

*Šis sertifikatas galioja tik tuo atveju, jei palaikomos kokybės sistemos sąlygos, atitinkančios direktyvos reikalavimus, kaip nurodo notifikuoti
įstaiga, atlikdama priežiūros veiklą.*

Šis sertifikatas išduotas elektroniniu būdu ir yra susietas su sutarties sąlygomis.

EB projekto patikros sertifikatas

Papildoma informacija dėl CE 620231

Kam išduota:

**Implantuojami širdies stimulatoriai,
Guidant Corporation bendrovei visiškai
priklausanti dukterinė įmonė
Boston Scientific Corporation bendrovei visiškai
priklausanti dukterinė įmonė
4100 Hamline Avenue North
St. Paul
Minnesota
55112-5798
JAV**

Sertifikato istorija

Data	Nuorodos Nr.	Veiksmai
2014 m. rugsėjo mėn. 26 d.	10150309	Pirmasis išdavimas, įskaitant modelį 2869, v2.01.

Pirmojo išdavimo data: **2014 m. rugsėjo mėn. 26 d.**Data: **2014 m. rugsėjo mėn. 26 d.**Galioja iki: **2019 m. rugsėjo mėn. 25 d.**

...kompetenciją paverčiame įpročiu™

Psl. 3 iš 3

Šis sertifikatas galioja tik tuo atveju, jei palaikomos kokybės sistemos sąlygos, atitinkančios direktyvos reikalavimus, kaip nurodo notifikuotoji įstaiga, atlikdama priežiūros veiklą.

Šis sertifikatas išduotas elektroniniu būdu ir yra susietas su sutarties sąlygomis.

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798
JAV

ATITIKTIES DEKLARACIJA

Gamintojas

Implantuojami širdies stimulatoriai,
Guidant Corporation bendrovei visiškai priklausanti dukterinė įmonė,
Boston Scientific Corporation bendrovei visiškai priklausanti dukterinė įmonė
4100 Hamline Avenue North
St. Paul, Minesota 55112-5798
JAV

Gamybos vieta

Boston Scientific Clonmel Limited
Cashel Road,
Clonmel, Co. Tipperary, Airija

ES įgaliotasis atstovas

Guidant Europe NV/SA
Green Square; Lambroekstraat 5D,
1831 Diegem, Belgija

Produktai

Modelio pavadinimas	Modelio numeris
ESSENTIO MRI	L110, L111, L131
PROPONENT MRI	L210, L211, L231
ACCOLADE MRI	L310, L311, L331
ALTRUA 2	S701, S702, S722
ESSENTIO	L100, L101, L121
PROPONENT	L200, L201, L209, L221
ACCOLADE	L300, L301, L321
VALITUDE CRT-P	U125
VALITUDE X4 CRT-P	U128
VISIONIST CRT-P	U225, U226
VISIONIST X4 CRT-P	U228
Taikomoji programinė įranga	2869 v2.01

Taikoma direktyva

Aktyviųjų implantuojamų medicinos prietaisų direktyva (90/385 / EEB)

Prietaiso klasifikacija

Aktyvusis implantuojamasis medicinos prietaisas

Atitikties patvirtinimo būdas

Tarybos direktyvos 90/385 / EEB (AIMDD) 2 priedas 4 skirsnis- produkto projekto patikra.

Pirminis išdavimas: Ingenio 2 ir ImageReady™ MR sąlyginė stimuliavimo sistema

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112–5798
JAV

Projekto patikros sertifikatas:

Sertifikato numeris: CE 620231 projekto patikra

Kas išdavė: Didžiosios *Britanijos* standartizacijos institucija (Britų standartų institutas) (BSI)
(Notifikuotoji įstaiga Nr. 0086)

Galiojimo data, iki: 2019 m. rugsėjo mėn. 25 d.

Kokybės valdymo sistemos sertifikatas

Sertifikato numeris: FM 71197 QMS - ISO 13485: 2003

Įregistravo: Didžiosios **Britanijos** standartizacijos institucija (BSI)

Visapusiškos kokybės užtikrinimo sertifikatas

Sertifikato numeris: CE 00027, visapusiškas kokybės užtikrinimas

Kas išdavė: Didžiosios **Britanijos** standartizacijos institucija (BSI) (Notifikuotoji įstaiga Nr. 0086)

Atitikties deklaracija

Aš pareiškiu, kad šiame dokumente paminėti prietaisai atitinka esminius aktyviųjų implantuojamųjų medicinos prietaisų direktyvos 90/385 / EEB reikalavimus ir sąlygas.

Įgaliojėji pasirašantys asmenys

Data: 2014 m. rugsėjo mėn. 26 d.

/parašas/

Kristen Harty, priežiūros reikalų vadovas

/parašas/

Renold Russie, kokybės užtikrinimo skyriaus viceprezidentas

/parašas/

Matt Tracy, programos valdymo skyriaus viceprezidentas

Pirminis išdavimas: Ingenio 2 ir ImageReady™ MR sąlyginė stimuliavimo sistema



EC Design-Examination Certificate

Directive 90/385/EEC on Medical Devices, Annex 2 Section 4

No. **CE 608954**
Issued To: **Cardiac Pacemakers, Incorporated**
a wholly owned subsidiary of Guidant
Corporation a wholly owned subsidiary of
Boston Scientific Corporation
4100 Hamline Avenue North
St Paul
Minnesota
55112-5798
USA

In respect of:

INGEVITY & INGEVITY MRI Leads & Accessories

BSI has performed a design examination on the above devices in accordance with the Council Directive 90/385/EEC, Annex 2 Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex 2 excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **26/02/2014**

Date: **26/02/2014**

Expiry Date: **25/02/2019**

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Page 1 of 3

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 608954

Issued To:

Cardiac Pacemakers, Incorporated
a wholly owned subsidiary of Guidant
Corporation a wholly owned subsidiary of
Boston Scientific Corporation
4100 Hamline Avenue North
St Paul
Minnesota
55112-5798
USA

Model Name	Model Number
INGEVITY	7631, 7632, 7635, 7636, 7640, 7641, 7642
INGEVITY MRI	7731, 7732, 7735, 7736, 7740, 7741, 7742
Suture Sleeve Accessory	6402
Delivery Stylet Accessories	5003, 5004, 5005, 5012, 5013, 5014, 6506, 6603

First Issued: **26/02/2014**

Date: **26/02/2014**

Expiry Date: **25/02/2019**

Page 2 of 3

Validity of this certificate is conditional on the quality surveillance activities of the Notified Body.
This certificate was issued electronically and is bound I

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 608954

Issued To:

Cardiac Pacemakers, Incorporated
a wholly owned subsidiary of Guidant
Corporation a wholly owned subsidiary of
Boston Scientific Corporation
4100 Hamline Avenue North
St Paul
Minnesota
55112-5798
USA

Certificate History

Date	Reference Number	Action
26 February 2014	10144947	First Issue

First Issued: **26/02/2014**

Date: **26/02/2014**

Expiry Date: **25/02/2019**

Page 3 of 3

Validity of this certificate is conditional on the quality surveillance activities of the Notified Body.
This certificate was issued electronically and is bound I

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

Boston Scientific
4100 Hamline Avenue North
St. Paul, Minnesota 55112

DECLARATION OF CONFORMITY

Manufacturer

Cardiac Pacemakers, Incorporated
a wholly owned subsidiary of Guidant Corporation,
a wholly owned subsidiary of Boston Scientific
4100 Hamline Avenue North
St. Paul, Minnesota 55112 USA

Manufacturing Site

Cardiac Pacemakers, Incorporated
a wholly owned subsidiary of Guidant Corporation,
a wholly owned subsidiary of Boston Scientific
4100 Hamline Avenue North
St. Paul, Minnesota 55112 USA

Guidant Puerto Rico B.V.
A wholly owned subsidiary of Boston Scientific Corporation
No. 12, Road No 698
Bo. Mameyal
Dorado, Puerto Rico 00646-3311

EU Authorized Representative

Guidant Europe NV/SA
Green Square; Lambroekstraat 5D,
B-1831 Diegem Belgium

Products

Model Name	Model Number
INGEVITY	7631, 7632, 7635, 7636, 7640, 7641, 7642
INGEVITY MRI	7731, 7732, 7735, 7736, 7740, 7741, 7742
Suture Sleeve Accessory	6402
Delivery Stylet Accessory	5003, 5004, 5005, 5012, 5013, 5014
Delivery Style Accessory	6506, 6603

Applicable Directive

Active Implantable Medical Devices Directive (90/385/EEC)

Device Classification

Active Implantable Medical Device

Issue #1: INGEVITY and INGEVITY MRI Leads & Accessories

Boston Scientific
4100 Hamline Avenue North
St. Paul, Minnesota 55112

Route to Conformity

Council Directive 90/385/EEC (AIMDD) Annex 2 Section 4 Examination of the Design of the Product

Quality Management System Certificate

Certificate Number: FM 71197 QMS - ISO 13485:2003
Registrar: The British Standards Institution (BSI)

Full Quality Assurance Certificate

Certificate Number: CE 00027 Full Quality Assurance
Issued By: The British Standards Institution (BSI) (Notified Body # 0086)

Design Examination Certificate

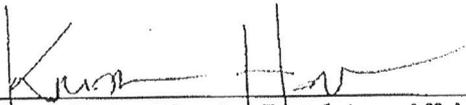
Certificate Number: CE 608954 Design Examination
Issued By: The British Standards Institution (BSI) (Notified Body # 0086)
Expiration Date: 25 February 2019

Declaration of Conformity

I hereby declare that the above mentioned devices comply with the Essential Requirements and Provisions of the Active Implantable Medical Devices Directive 90/385/EEC

Authorized Signatory

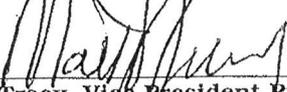
Date 26 February 2014



Kristen Harty, Director Regulatory Affairs



Renold Russie, Vice President Quality Assurance



Matt Tracy, Vice President Program Management

bsi.



EB projekto patikrinimo sertifikatas

Tarybos direktyva dėl medicinos prietaisų Nr. 90/385/EEC, 2 priedas, 4 skyrius

Nr.

CE 608954

Išduota:

širdies stimulatorius gaminančiai įmonei, įregistruotai kaip dukterinė įmonė, valdoma motininės korporacijos „Boston Scientific Corporation“
4100 Hamline Avenue North
St Paul
Minesota
55112-5798
JAV

Dėl:

INGEVITY & INGEVITY MRI laidininkų ir priedų

Vadovaujantis Tarybos direktyvos Nr. 90/385/EE, 2 priedo 4 skyriaus nuostatomis, BSI atliko minėtų medicinos prietaisų projekto patikrinimą. Projektas atitinka šios direktyvos reikalavimus. Minėtų produktų pardavimui yra būtina gauti papildomą sertifikatą, apibūdintą šios direktyvos Priede Nr. 2 (nejsk. 4 skyriaus).

BSI vardu, notifikuota įstaiga, atsakinga už šio direktyvos reikalavimų vykdymą (notifikuotos įstaigos Nr. 0086):

/parašas/

Garis Fentonas, globalus draudimo direktorius

Pirmas leidimas: **2014-02-26**

Data: **2014-02-26**

Galiojimo data: **2019-02-25**

... tegul kokybė tampa įpročiu“.

1 lapas iš 3

Šio sertifikato galiojimas tiesiogiai susijęs su kokybės valdymo sistema, kuri yra įdiegta ir palaikoma pagal direktyvos reikalavimus, kas yra patvirtinta notifikuotos įstaigos nuolatinės priežiūros vykdomų veiksmų.

Šis sertifikatas išduodamas elektroninėje erdvėje ir jam taikomos pagrindinės sutarties sąlygos.

Informacija ir kontaktai: BSI, Kitemark Court, Davy Avenue, Knowhill, Millton Keynes MK5 8PP. Tel. +44 845 080 9000
BSI Assurance UK Limited, registruota Anglijoje, registracijos numeris 7805321, adresas 389 Chiswick High Road, Londonas W4 4AL, Didžioji Britanija.
BSI įmonių grupės narė.

EB projekto patikrinimo sertifikatas

Papildoma informacija prie CE 608954

Ištuota: širdies stimulatorius gaminančiai įmonei, įregistruotai kaip dukterinė įmonė, valdoma motininės korporacijos „Boston Scientific Corporation“
4100 Hamline Avenue North
St Paul
Minesota
55112-5798
JAV

Modelis	Modelio numeris
INGEVITY	7631, 7632, 7635, 7636, 7640, 7641, 7642
INGEVITY MRI	7731, 7732, 7735, 7736, 7740, 7741, 7742
Širdies stimulatoriaus tvirtinimo rankovės priedai	6402
Kateterio priedai	5003, 504, 5005, 5012, 5013, 5014, 6506, 6603

Pirmas leidimas: 2014-02-26

Data: 2014-02-26

Galiojimo data: 2019-02-25

... tegul kokybė tampa įpročiu“.

2 lapas iš 3

Šio sertifikato galiojimas tiesiogiai susijęs su kokybės valdymo sistema, kuri yra įdiegta ir palaikoma pagal direktyvos reikalavimus, kas yra patvirtinta notifikuotos įstaigos nuolatinės priežiūros vykdomų veiksmų.

Šis sertifikatas išduodamas elektroninėje erdvėje ir jam taikomos pagrindinės sutarties sąlygos.

Informacija ir kontaktai: BSI, Kitemark Court, Davy Avenue, Knowhill, Millton Keynes MKS 8PP. Tel. +44 845 080 9000
BSI Assurance UK Limited, registruota Anglijoje, registracijos numeris 7805321, adresas 389 Chiswick High Road, Londonas W4 4AL, Didžioji Britanija.
BSI įmonių grupės narė.

EB projekto patikrinimo sertifikatas
Papildoma informacija prie CE 608954

Išduota: širdies stimulatorius gaminančiai įmonei, įregistruotai kaip dukterinė įmonė, valdoma motininės korporacijos „Boston Scientific Corporation“
4100 Hamline Avenue North
St Paul
Minnesota
55112-5798
JAV

Sertifikavimo istorija

Data	Numeris	Veiksmas
2014 m. vasario 26 d.	10144947	Pirmasis leidimas

Pirmas leidimas: **2014-02-26**

Data: **2014-02-26**

Galiojimo data: **2019-02-25**

... tegul kokybė tampa įpročiu“.

3 lapas iš 3

Šio sertifikato galiojimas tiesiogiai susijęs su kokybės valdymo sistema, kuri yra įdiegta ir palaikoma pagal direktyvos reikalavimus, kas yra patvirtinta notifikuotos įstaigos nuolatinės priežiūros vykdomų veiksmų.

Šis sertifikatas išduodamas elektroninėje erdvėje ir jam taikomos pagrindinės sutarties sąlygos.

Informacija ir kontaktai: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MKS 8PP. Tel. +44 845 080 9000
BSI Assurance UK Limited, registruota Anglijoje, registracijos numeris 7805321, adresas 389 Chiswick High Road, Londonas W4 4AL, Didžioji Britanija.
BSI įmonių grupės narė.

„Boston Scientific Corporation“
4100 Hamline Avenue North
St Paul, Minesota 55112-5798

ATITIKTIES DEKLARACIJA

Gamintojas

širdies stimulatorius gaminanti įmonė, įregistruotai kaip
dukterinė įmonė, valdoma motininės korporacijos „Guidant Corporation“, valdomos motininės
korporacijos „Boston Scientific Corporation“
4100 Hamline Avenue North
St. Paul, Minesota 55112, JAV

Gamybos aikštelė

širdies stimulatorius gaminanti įmonė, įregistruotai kaip
dukterinė įmonė, valdoma motininės korporacijos „Guidant Corporation“, valdomos motininės
korporacijos „Boston Scientific Corporation“
4100 Hamline Avenue North
St. Paul, Minesota 55112, JAV

Guidant Puerto Rico B.V.

dukterinė įmonė, valdoma motininės korporacijos „Boston Scientific Corporation“

Nr. 12, Kelias Nr. 698

Bo. Mameyal

Dorado, Puerto Rikas 00646-3311

ES įgaliotoji institucija

Guidant Europe NV/SA

Green Square; Lambroekstraat 5D,

B-1831 Diegem, Belgija

Produktai

Modelis	Modelio numeris
INGEVITY	7631, 7632, 7635, 7636, 7640, 7641, 7642
INGEVITY MRI	7731, 7732, 7735, 7736, 7740, 7741, 7742
Širdies stimulatoriaus tvirtinimo rankovės priedai	6402
Kateterio priedai	5003, 504, 5005, 5012, 5013, 5014,
Kateterio priedai	6506, 6603

Taikoma direktyva

Aktyvių implantuojamų medicinos prietaisų direktyva Nr. 90/385/EEB

Prietaiso klasifikacija

Aktyvus implantuojamas medicinos prietaisas

„Boston Scientific Corporation“
4100 Hamline Avenue North
St Paul, Minesota 55112-5798

Nurodą į atitikimą

Tarybos direktyvos 90/385/EEB (AIMDD) 2 priedo 4 skyrius – Produkto projekto patikrinimas

Kokybės vadybos sistemos sertifikatas

Sertifikato Numeris: FR 71197 QMS-ISO 13485:2003

Registruotojas: Didžiosios Britanijos standartizavimo institucija (BSI)

Visas kokybės užtikrinimo sertifikatas

Sertifikato Numeris: CE 00027 Visas kokybės užtikrinimas

Išdavė: Didžiosios Britanijos standartizavimo institucija (BSI) (notifikuota institucija Nr. 0086)

Projekto patikrinimo sertifikatas

Sertifikato Numeris: CE 608954 Projekto patikrinimas

Išdavė: Didžiosios Britanijos standartizavimo institucija (BSI) (notifikuota institucija Nr. 0086)

Galioja: 2019 m. vasario 25 d.

Atitikties deklaracija

Šiuo dokumentu patvirtiname, kad minėti prietaisai atitinka aktyvių implantuojamų medicinos prietaisų direktyvos Nr. 90/385/EEB esminius reikalavimus ir nuostatas.

Įgaliotoji pasirašančioji šalis

Data 2014 m. vasario 26 d.

/parašas/

Kristen Harty, Teisėtvarkos ir normatyvinių aktų skyriaus direktorė

/parašas/

Renold Russie, kokybės užtikrinimo viceprezidentas

/parašas/

Matt Tracy, programinio valdymo viceprezidentas



EC Certificate - Full Quality Assurance System

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

No.

CE 616288

Issued To:

**Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **30 June 2014**

Date: **22 September 2016**

Expiry Date: **25 September 2021**

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Page 1 of 2

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.

Certificate No: CE 616288

Certificate Scope:

Design, Development, and Manufacturing of Guidewires, Angiographic Catheters, Guide Catheters, Radio Frequency Ablation Catheters, Diagnostic Mapping, Pacing, and Recording Catheters, Mapping Systems, Electrosurgical Electrodes, and Generators, Recording and Amplifier Systems, Including Software, Percutaneous Catheters, Stents, Needles, Dilators, Accessories, Introducer Catheter, Drainage and Urological Catheters, Urological Irrigation, Biliary Devices, Biopsy Devices, Retrieval Devices, Nephrostomy Devices, Feeding Devices, Ligators, Polypectomy Devices, Hemostasis Devices, Sphinctertomes, Suturing Devices, Endoscopes, Endoscopic Drainage Stents, Delivery Systems and Endoscopic Access Devices, Atrial Appendage Closure Devices and Sterile Delivery Systems, and minimally invasive tissue and thrombus removal devices.

Those aspects of Annex II related to securing and maintaining the sterility in the manufacture of the ACUITY LDS Accessories, Cannulas, Fluid Administration Devices, Exchange Devices, Umbilical Cables, Cables and Accessories. Those aspects of Annex II related to maintaining the metrology function of inflators and accessory devices.

First Issued: **30 June 2014**

Date: **22 September 2016**

Expiry Date: **25 September 2021**

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Page 2 of 2

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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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 616288**
 Date: **22 September 2016**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Subcontractor:	Service(s) supplied
Availmed S.A. de C.V. C. Industrial Lt. 001 Mz. 105 No. 20905 Int. A Col. Cd. Industrial Tijuana, Baja California 22444 Mexico	Manufacture
Availmed S.A. de C.V. Ave. Paseo Reforma No. 8950 C.P. 22116 La Mesa, Tijuana, Baja California Mexico	Manufacture
Bard Electrophysiology A Division of C.R. Bard Inc. 55 Technology Drive Lowell MA 01851 USA	Design

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Marlborough
Massachusetts
01752
USA**

Subcontractor:	Service(s) supplied
Bard Glens Falls Operation 289 Bay Road Queensbury New York 12804 USA	Manufacture
Boston Scientific Corporation 100 Boston Scientific Way Marlborough MA 01752 USA	Design
Boston Scientific Corporation 150 Baytech Drive San Jose CA 95134 USA	Labelling Manufacture Packaging
Boston Scientific Corporation 2546 First Street Propark, El Coyol, Alajuela Costa Rica	Manufacture

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 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 47215 Lakeview Boulevard Fremont California 94538 USA	Manufacture

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Marlborough
Massachusetts
01752
USA

Subcontractor:	Service(s) supplied
Boston Scientific Corporation 5905 Nathan Lane Plymouth Minnesota 55442 USA	Manufacture
Boston Scientific Corporation 780 Brookside Drive Spencer IN 47460 USA	Manufacture
Boston Scientific Corporation Two Scimed Place Maple Grove Minnesota 55311 USA	Design Manufacture

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USA

Subcontractor:	Service(s) supplied
Boston Scientific Limited Ballybrit Business Park Galway Ireland	EU Representative Manufacture
Boston Scientific Limited Business and Technology Park Model Farm Road Cork Ireland	Manufacture
Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland	Labelling Manufacture
Brivant Ltd Parkmore West Business Park Galway Ireland	Manufacture

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01752
USA**

Subcontractor:

Service(s) supplied

BSC Coventry
8 Industrial Drive
Coventry
Rhode Island
02816
USA

ETO Sterilization

Creation Technologies LP
3939 North Fraser Way
Burnaby
British Columbia V5J 5J2
Canada

Manufacture

Creation Technologies LP
8977-8999 Fraserton Court
Burnaby
British Columbia V5J 5H8
Canada

Manufacture

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USA**

Subcontractor:	Service(s) supplied
Dedicated Computing LLC N26 W23880 Commerce Circle Waukesha Wisconsin 53188 USA	Crucial Supplier
FMD. Co., Ltd. 1-166 Shimo-obari-nakashima Komaki-shi Aichi 485-0051 Japan	Design 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
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318-1029 USA	Control of Sterilization Manufacture
Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern PA 19355 USA	Manufacture

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USA**

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
Nothern Digital, Inc. (NDI) 103 Randall Drive Waterloo Ontario N2V 1C5 Canada	Manufacture

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300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA**

Subcontractor:	Service(s) supplied
Nutek Corporation 1001 Whipple Road Hayward CA 94544 USA	E beam Sterilization
Rhythmia Medical Inc. 111 S. Bedford Street Suite 205 Burlington MA 01803 USA	Design
Rhythmia Medical Inc. 125 Cambridgepark Drive Cambridge MA 02140 USA	Design

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300 Boston Scientific Way
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Massachusetts
01752
USA

Subcontractor:	Service(s) supplied
Stellartech Research Corp. 560 Cottonwood Drive Milipitas CA 95035 USA	Manufacture
Sterigenics U.S. Inc. 7775 South Quincy Street Willowbrook Illinois 60527 USA	ETO Sterilization
Sterigenics 10811 Withers Cove Park Dr. Charlotte NC 28278 USA	Gamma Sterilization

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Marlborough
Massachusetts
01752
USA**

Subcontractor:	Service(s) supplied
Sterigenics 84 Park Road Queensbury NY 12804 USA	ETO Sterilization
STERIS ISOMEDIX Services, Inc 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
STERIS Isomedix Services 1880 Industrial Drive Libertyville Illinois 60048 USA	Gamma Sterilization

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