

สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ BEL 6302205

วันที่อนุมัติ 24/3/2563

วันที่หมดอายุ 11/2/2568

หน้า 2 / 2

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefitemNo
4775	847		CD2377-36Q	Ellipse DR		Ellipse DR	3	12913	37265	6300847000027
4775	847		CD2377-36QC	Ellipse DR		Ellipse DR	3	12913	37265	6300847000028
4775	848		CD2377-36	Ellipse DR		Ellipse DR	3	12913	37265	6300848000021
4775	848		CD2377-36C	Ellipse DR		Ellipse DR	3	12913	37265	6300848000022
4775	848		CD1377-36	Ellipse VR		Ellipse VR	3	12913	35852	6300848000023
4775	848		CD1377-36C	Ellipse VR		Ellipse VR	3	12913	35852	6300848000024
4775	848		CD1377-36Q	Ellipse VR		Ellipse VR	3	12913	35852	6300848000025
4775	848		CD1377-36QC	Ellipse VR		Ellipse VR	3	12913	35852	6300848000026
4775	848		CD2377-36Q	Ellipse DR		Ellipse DR	3	12913	37265	6300848000027
4775	848		CD2377-36QC	Ellipse DR		Ellipse DR	3	12913	37265	6300848000028
4775	4775		CD2377-36	Ellipse DR		Ellipse DR	3	12913	37265	6304775000001
4775	4775		CD2377-36C	Ellipse DR		Ellipse DR	3	12913	37265	6304775000002
4775	4775		CD1377-36	Ellipse VR		Ellipse VR	3	12913	35852	6304775000003
4775	4775		CD1377-36C	Ellipse VR		Ellipse VR	3	12913	35852	6304775000004
4775	4775		CD1377-36Q	Ellipse VR		Ellipse VR	3	12913	35852	6304775000005
4775	4775		CD1377-36QC	Ellipse VR		Ellipse VR	3	12913	35852	6304775000006
4775	4775		CD2377-36Q	Ellipse DR		Ellipse DR	3	12913	37265	6304775000007
4775	4775		CD2377-36QC	Ellipse DR		Ellipse DR	3	12913	37265	6304775000008

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)
FREE SALE CERTIFICATE
Active Implantable Medical Devices (AIMD)

N° of Certificate:

Exporting (certifying) country: Belgium

Importing (requesting) country: Thailand

SECTION TO BE COMPLETED BY THE APPLICANT OF THE CERTIFICATE

1. Name of AIMDs:

Implantable Cardioverter/Defibrillators (models in attached list)

1.1. Grouping according to Directive 90/385/EC: @ AIMD

1.2. Description (according to the type of the device):

Single-chamber implantable defibrillator (GMDN 35852), Dual-chamber implantable defibrillator (GMDN 37265)

1.3. Does the product contain animal substances?

No

If yes, which animal substance?

1.4. Does the product contain medicinal substances?

No

If yes, which medicinal substance?

1.5. Does the product contain radioactive substances?

No

If yes, which radioisotope and how much Becquerel?

1.6. Is this product authorized to be placed on the market for use in the exporting country?

Yes

1.7. Is this product actually on the market in the exporting country?

Yes

1.8. Does the exported product carry the CE mark according to Directive 90/385/EC?

Yes

2. Information regarding the manufacturer:

2.1. Manufacturer (according to the definition of Directive 90/385/EC): name and address:

St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 box F1, 1935 Zaventem, Belgium

2.2. Applicant for certificate:

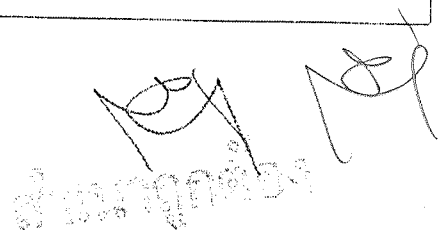
St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 box F1, 1935 Zaventem, Belgium

2.3. Name and number of the Notified Body: TÜV SÜD - # 0123

2.4. Has the manufacturer been certified to be in compliance with ISO 9000/ EN 13485 standards? Yes




If yes state the name of the organisation that delivered the certificate: TÜV SÜD - # 0123



If no, please explain:



RESERVED FOR THE ADMINISTRATION

The AIMD as described above is presumed to meet the applicable provisions of Council Directive 90/385/EC and can be placed on the market in the exporting country.

Address of certifying authority:	FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS EUROSTATION II, Victor Hortaplein 40 bus 40, 1060 BRUSSELS (BELGIUM) Telephone n°: +32 2 528.40.00	
Date:		Name of authorized person: Xavier De Cuyper Chief Executive Officer
Stamp:		 



ATTACHMENT TO THE FREE SALE CERTIFICATE BELGIUM/THAILAND
"Models & components"

Device Name	Model Number	GMDN Code
Ellipse™ DR	CD2377-36, CD2377-36C	37265
Ellipse™ VR,	CD1377-36, CD1377-36C	35852
Ellipse™ VR	CD1377-36Q, CD1377-36QC	35852
Ellipse™ DR	CD2377-36Q, CD2377-36QC	37265

Manufacturing sites:

- St. Jude Medical Coordination Center BVBA, The Corporate Village, De Vincilaan 11 F1, 1935 Zaventem, Belgium
- St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
- St. Jude Medical Puerto Rico LLC, Lot A Interior - #2 Rd km 67.5, Santana Industrial Park, Arecibo, PR 00612, USA
- St. Jude Medical Operations (M) Sdn. Bhd., Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, Malaysia

EC DECLARATION OF CONFORMITY
Implantable Cardioverter/Defibrillators

St. Jude Medical Coordination Center BVBA hereby declares that the following facilities and devices conform to the applicable provisions of Annex 2 of the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (AIMD). All supporting documentation is retained under the premises of St. Jude Medical Coordination Center BVBA. We declare no application has been lodged with any other notified body for the same devices. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same devices.

Legal Manufacturer:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium
Device Type:	Implantable Defibrillator; Cardiac Resynchronization Therapy – Defibrillator
Device Name(s):	Ellipse™; Fortify Assura™; Unify Assura™; Quadra Assura™; Quadra Assura MP™
Model Number(s):	See attachment
Classification:	AIMD
GMDN Code(s):	See attachment
Original CE Mark Date:	22 August 2013
Full Quality Assurance Certificate No and expiration date:	Certificate No: I1 16 07 48277 031 Expiration Date: 2021-07-25
EC Design-Examination Certificate No and expiration date:	Certificate No: I7 17 10 48277 035 Expiration Date: 2022-09-25
Applicable Quality System Standards:	EN ISO 13485:2012
Quality System Certificate No and expiration date:	Certificate No: Q5 18 05 48277 036 Expiration Date: 2021-05-29
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle, Ridderstraße 65, 80339 Munich, Germany
Notified Body Number:	0123
Manufacturing Facilities:	St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court, Sylmar, CA 91342 USA St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo, Puerto Rico 00612 USA St. Jude Medical Operations (M) Sdn. Bhd. Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang Malaysia

EC DECLARATION OF CONFORMITY
Implantable Cardioverter/Defibrillators

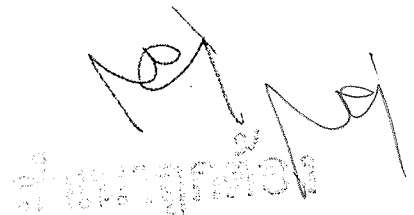
Signature:



Roland Back
Director Regulatory Affairs, EMEA
St. Jude Medical

15-AUGUST-2018.

Issue Date



EC DECLARATION OF CONFORMITY
Implantable Cardioverter/Defibrillators

ATTACHMENT: List of Devices covered by the Declaration of Conformity

Device Type	Device Name	Model Number	GMDN Code
Single-Chamber Implantable Defibrillator	Ellipse™ VR	CD1377-36C	35852
		CD1377-36QC*	
		CD1411-36QC*	
		CD1377-36	
		CD1377-36Q*	
		CD1411-36Q*	
	Fortify Assura™ VR	CD1359-40C	
		CD1359-40QC*	
		CD1359-40	
		CD1359-40Q*	
Dual-Chamber Implantable Defibrillator	Ellipse™ DR	CD2377-36C	37265
		CD2377-36QC*	
		CD2411-36QC*	
		CD2377-36	
		CD2377-36Q*	
		CD2411-36Q*	
	Fortify Assura™ DR	CD2359-40C	
		CD2359-40QC*	
		CD2359-40	
		CD2359-40Q*	
Cardiac Resynchronization Therapy – Defibrillator (CRT-D)	Unify Assura™	CD3361-40C	47270
		CD3361-40QC	
		CD3361-40	
		CD3361-40Q	
	Quadra Assura™	CD3367-40C	
		CD3367-40QC*	
		CD3367-40	
		CD3367-40Q*	
	Quadra Assura MP™	CD3371-40C	
		CD3371-40QC*	
		CD3371-40	
		CD3371-40Q*	

* MR Conditional models

Handwritten signature and date: 2/17/2017



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. 17 17 10 48277 035

Manufacturer: St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
BELGIUM

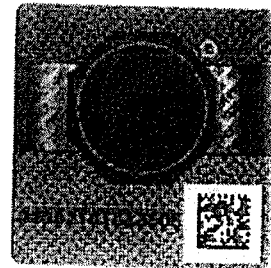


Product: Implantable Cardioverter / Defibrillators

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713115892

Valid from: 2018-02-12
Valid until: 2022-09-25



Date, 2018-02-12

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0129

Page 1 of 2



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. 17 17 10 48277 035

Model(s): see attachment

Parameters: /

Facility(ies):
St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo
PR 00612, USA

St. Jude Medical Operations (M) Sdn.Bhd.
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial
Zone, 11900 Penang, MALAYSIA

St. Jude Medical Coordination Center BVBA
European Distribution Center, BruCargo 831, 1931 BruCargo,
BELGIUM

Design
Facility(ies): St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA



Product Service

Attachment for Certificate no I7 17 10 48277 035
dated 2018-02-12

Product: Implantable Cardioverter / Defibrillators

Test Report: 713026877

Model:	Model no.:	Variant:
Quadra Assura™ IS-1/DF-1 DF-4	CD3367-40, CD3367-40Q,	CD3367-40C CD3367-40QC MR Conditional
Quadra Assura MP™ IS-1/DF-1 DF-4	CD3371-40, CD3371-40Q,	CD3371-40C CD3371-40QC MR Conditional
Unify Assura™ IS-1/DF-1 DF-4	CD3361-40, CD3361-40Q,	CD3361-40C CD3361-40QC
Fortify Assura™ DR IS-1/DF-1 DF-4	CD2359-40, CD2359-40Q,	CD2359-40C CD2359-40QC MR Conditional
Fortify Assura™ VR IS-1/DF-1 DF-4	CD1359-40, CD1359-40Q,	CD1359-40C CD1359-40QC MR Conditional
Ellipse™ DR IS-1/DF-1 DF-4	CD2377-36, CD2377-36Q	CD2377-36C CD2377-36QC MR Conditional
Ellipse™ VR IS-1/DF-1 DF-4	CD1377-36, CD1377-36Q,	CD1377-36C CD1377-36QC MR Conditional



Product Service

Attachment for Certificate no I7 17 10 48277 035
dated 2018-02-12

Test Report: 713115892

Model:	Model no.:	Variant:
Ellipse™ DR DF-4	CD2411-36Q, CD2411-36QC	MR Conditional
Ellipse™ VR DF-4	CD1411-36Q, CD1411-36QC	MR Conditional

Munich, MHS-CRT, 2018-02-12

Stefan Preiß
Certification Medical Technology

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

EC Certificate

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. 11 16 07 48277 031

Manufacturer:

**St. Jude Medical
Coordination Center BVBA**

The Corporate Village
De Vincilaan 11 Box F1
1935 Zaventem
BELGIUM



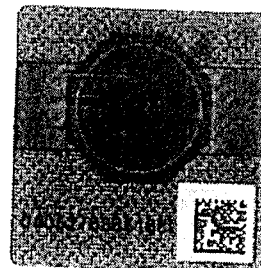
Product:

**Brady and Tachy IPGs, Implantable Leads for AIMDs,
Programmers and Accessory Devices for AIMDs,
Implantable Monitoring and Recording Systems,
Application Software (external), Cardiac Rhythm
Management Device Accessories (includes items
such as adapters, stylets, guidewires, tools)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report No.: 713078152

Valid from: 2016-07-26
Valid until: 2021-07-25



Stefan Preiß
Stefan Preiß

Date, 2016-07-25

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ♦ CERTIFICATE ♦ 認証証書 ♦ CERTIFICADO ♦ CERTIFICAT



Product Service

**EC Certificate
Full Quality Assurance System**

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. 11 16 07 48277 031

Facility(ies):

St. Jude Medical Coordination Center BVBA
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,
BELGIUM

St. Jude Medical Coordination Center BVBA
European Distribution Center, BruCargo 631, 1931 BruCargo,
BELGIUM

St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo
PR 00612, USA

St. Jude Medical Operations (M) Sdn.Bhd.
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial
Zone, 11900 Penang, MALAYSIA

**Design
Facility(ies):**

St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE



Product Service

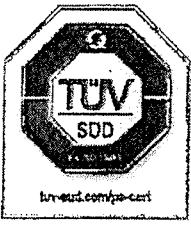
CERTIFICATE

No. Q5 18 05 48277 036

Holder of Certificate: St. Jude Medical
Coordination Center BVBA

The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
BELGIUM

Certification Mark:



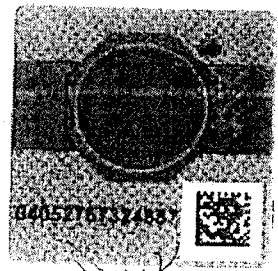
Scope of Certificate: Design and Development, Production and Distribution of Brady and Tachy IPCs, Implantable Leads for AIMDs, Programmers and Accessory Devices for AIMDs, Implantable Monitoring and Recording Systems, Application Software (external), Cardiac Rhythm Management Device Accessories (includes items such as adapters, stylets, guidewires, tools)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713126935

Valid from: 2018-05-30

Valid until: 2021-05-29



Date: 2018-05-11

Stefan Preiß
Stefan Preiß

[Handwritten signatures]

Page 1 of 2

DAkkS

Deutsche
Akreditierungsstelle
D-224-15721-01-05



3AK-Q CERT2 10 E

ZERTIFIKAT ♦ CERTIFICATE ♦ 認証証書 ♦ CERTIFICADO ♦ CERTIFICAT



Product Service

CERTIFICATE
No. Q5 18 05 48277 036

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):
St. Jude Medical Coordination Center BVBA
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,
BELGIUM

St. Jude Medical Coordination Center BVBA
European Distribution Center, BruCargo 831, 1931 BruCargo,
BELGIUM





ใบอนุญาตนำเข้าเครื่องมือแพทย์

ใบอนุญาตที่ 65-2-1-2-0005261

ใบอนุญาตฉบับนี้ให้ไว้แก่

บริษัท แอ็บบอต เมดิคัล (ประเทศไทย) จำกัด

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ สน. 505/2554

เพื่อแสดงว่าเป็นผู้รับอนุญาตนำเข้าเครื่องมือแพทย์ตามมาตรา ๑๗ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

Durata Defibrillation Leads

รายละเอียดเครื่องมือแพทย์

ตามเอกสารแนบท้าย

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์

ตามเอกสารแนบท้าย

ณ สถานที่นำเข้าเครื่องมือแพทย์ของบริษัท แอ็บบอต เมดิคัล (ประเทศไทย) จำกัด

ตั้งอยู่เลขที่

555 อาคารรสา ทาวเวอร์ 2 ชั้น 17 ยูนิต 1704

ตรอก/ซอย

ถนน

พหลโยธิน

หมู่ที่

ตำบล/แขวง

จตุจักร

อำเภอ/เขต

จตุจักร

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์

10900

โทรศัพท์ 0 2796 6555

โทรสาร

0 2937 1148

ชื่อและที่ตั้งของเจ้าของผลิตภัณฑ์

St. Jude Medical 15900 Valley View Court Sylmar, CA USA 91342

ใบอนุญาตนำเข้าฉบับนี้ใช้ได้จนถึงวันที่ 31 ธันวาคม พ.ศ.

2569

และให้ใช้เฉพาะสถานที่ซึ่งระบุไว้

ในใบอนุญาตเท่านั้น

ออกให้ ณ วันที่

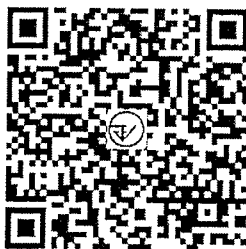
29

เดือน

มีนาคม

พ.ศ.

2565

สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

ผู้อนุญาต

เอกสารแนบท้าย

ใบอนุญาตนำเข้าที่ 65-2-1-2-0005261

รายละเอียดเครื่องมือแพทย์

The Durata transvenous leads are indicated for use with compatible pulse generators. They provide pacing, sensing and deliver cardioversion/defibrillation therapy to the heart.

A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation.

มีรายละเอียดรายการเครื่องมือแพทย์ หรืออุปกรณ์เสริม ดังนี้

NEWCODE	ชื่อผลิตภัณฑ์	identifier	บริษัทผู้ผลิต	อื่นๆ
6548321000025	Durata Defibrillation Leads	7120/60	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 60
6548321000028	Durata Defibrillation Leads	7120/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 65
6548321000031	Durata Defibrillation Leads	7120/75	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 75
6548321000034	Durata Defibrillation Leads	7120Q/52	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 75
6548321000037	Durata Defibrillation Leads	7120Q/58	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 58
6548321000040	Durata Defibrillation Leads	7120Q/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 65
6548321000043	Durata Defibrillation Leads	7121/60	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 60
6548321000046	Durata Defibrillation Leads	7121/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 65

NEWCODE	ชื่อผลิตภัณฑ์	identifier	บริษัทผู้ผลิต	อื่นๆ
6548321000069	Durata Defibrillation Leads	7121/75	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 75
6548321000052	Durata Defibrillation Leads	7121Q/52	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 52
6548321000055	Durata Defibrillation Leads	7121Q/58	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 58
6548321000058	Durata Defibrillation Leads	7121Q/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Dual, 17 x 65
6548321000061	Durata Defibrillation Leads	7122/60	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Single x 60
6548321000064	Durata Defibrillation Leads	7122/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Single x 65
6548321000067	Durata Defibrillation Leads	7122/75	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Single x 75
6548321000070	Durata Defibrillation Leads	7122Q/52	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Single x 52
6548321000073	Durata Defibrillation Leads	7122Q/58	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Single x 58
6548321000076	Durata Defibrillation Leads	7122Q/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Active x Single x 65
6548321000079	Durata Defibrillation Leads	7170/60	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 17 x 60
6548321000082	Durata Defibrillation Leads	7170/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 17 x 65

NEWCODE	ชื่อผลิตภัณฑ์	identifier	บริษัทผู้ผลิต	อื่นๆ
6548321000085	Durata Defibrillation Leads	7170/75	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 17 x 75
6548321000088	Durata Defibrillation Leads	7170Q/52	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 17 x 52
6548321000091	Durata Defibrillation Leads	7170Q/58	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 17 x 58
6548321000094	Durata Defibrillation Leads	7170Q/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 17 x 65
6548321000097	Durata Defibrillation Leads	7171/60	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 21 x 60
6548321000100	Durata Defibrillation Leads	7171/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 21 x 65
6548321000103	Durata Defibrillation Leads	7171/75	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 21 x 75
6548321000106	Durata Defibrillation Leads	7171Q/52	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 21 x 52
6548321000109	Durata Defibrillation Leads	7171Q/58	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 21 x 58
6548321000112	Durata Defibrillation Leads	7171Q/65	ST. JUDE MEDICAL PUERTO RICO, LLC (USA) LOT A INTERIOR - No. 2 ST KM 67.5 SANTANA INDUSTRIAL PARK Arecibo Puerto Rico USA 00612	True Bipolar x Passive x Dual, 21 x 65
6548324000022	Durata Defibrillation Leads	7120/60	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuh raya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 60
6548324000025	Durata Defibrillation Leads	7120/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuh raya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 65
6548324000028	Durata Defibrillation Leads	7120/75		


NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
			ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 75
6548324000031	Durata Defibrillation Leads	7120Q/52	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 75
6548324000034	Durata Defibrillation Leads	7120Q/58	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 58
6548324000037	Durata Defibrillation Leads	7120Q/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 65
6548324000040	Durata Defibrillation Leads	7121/60	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 60
6548324000043	Durata Defibrillation Leads	7121/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 65
6548324000046	Durata Defibrillation Leads	7121/75	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 75
6548324000049	Durata Defibrillation Leads	7121Q/52	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 52
6548324000052	Durata Defibrillation Leads	7121Q/58	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 58
6548324000055	Durata Defibrillation Leads	7121Q/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Dual, 17 x 65

NEWCODE	ชื่อผลิตภัณฑ์	identifier	บริษัทผู้ผลิต	อื่นๆ
654832400068	Durata Defibrillation Leads	7122/60	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Single x 60
654832400061	Durata Defibrillation Leads	7122/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Single x 65
654832400064	Durata Defibrillation Leads	7122/75	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Single x 75
654832400067	Durata Defibrillation Leads	7122Q/52	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Single x 52
654832400070	Durata Defibrillation Leads	7122Q/58	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Single x 58
654832400073	Durata Defibrillation Leads	7122Q/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Active x Single x 65
654832400076	Durata Defibrillation Leads	7170/60	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 17 x 60
654832400079	Durata Defibrillation Leads	7170/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 17 x 65
654832400082	Durata Defibrillation Leads	7170/75	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 17 x 75
654832400085	Durata Defibrillation Leads	7170Q/52	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 17 x 52

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
6548324000088	Durata Defibrillation Leads	7170Q/58	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 17 x 58
6548324000091	Durata Defibrillation Leads	7170Q/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 17 x 65
6548324000094	Durata Defibrillation Leads	7171/60	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 21 x 60
6548324000097	Durata Defibrillation Leads	7171/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 21 x 65
6548324000100	Durata Defibrillation Leads	7171/75	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 21 x 75
6548324000103	Durata Defibrillation Leads	7171Q/52	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 21 x 52
6548324000106	Durata Defibrillation Leads	7171Q/58	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 21 x 58
6548324000109	Durata Defibrillation Leads	7171Q/65	ST. JUDE MEDICAL OPERATIONS (M) SDN BHD (MALAYSIA) Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang MYS 11900	True Bipolar x Passive x Dual, 21 x 65
6550652000022	Durata Defibrillation Leads	7120/60	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 60
6550652000025	Durata Defibrillation Leads	7120/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 65
6550652000028	Durata Defibrillation Leads	7120/75	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 75
6550652000031	Durata Defibrillation Leads	7120Q/52	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION	True Bipolar x Active x Dual, 17

NEWCODE	ชื่อผลิตภัณฑ์	identifier	บริษัทผู้ผลิต	อื่นๆ
			(USA) 15900 Valley View Court SYLMAR California USA 91342	x 75
6550652000034	Durata Defibrillation Leads	7120Q/58	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 58
6550652000037	Durata Defibrillation Leads	7120Q/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 65
6550652000040	Durata Defibrillation Leads	7121/60	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 60
6550652000043	Durata Defibrillation Leads	7121/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 65
6550652000046	Durata Defibrillation Leads	7121/75	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 75
6550652000049	Durata Defibrillation Leads	7121Q/52	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 52
6550652000052	Durata Defibrillation Leads	7121Q/58	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 58
6550652000055	Durata Defibrillation Leads	7121Q/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Dual, 17 x 65
6550652000058	Durata Defibrillation Leads	7122/60	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Single x 60
6550652000061	Durata Defibrillation Leads	7122/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Single x 65
6550652000064	Durata Defibrillation Leads	7122/75	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Single x 75
6550652000067	Durata Defibrillation Leads	7122Q/52	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Single x 52
6550652000070	Durata Defibrillation Leads	7122Q/58	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Single x 58
6550652000073	Durata Defibrillation Leads	7122Q/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Active x Single x 65
6550652000076	Durata Defibrillation Leads	7170/60	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION	True Bipolar x Passive x Dual, 17 x 60

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
			(USA) 15900 Valley View Court SYLMAR California USA 91342	
6550652000079	Durata Defibrillation Leads	7170/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 17 x 65
6550652000082	Durata Defibrillation Leads	7170/75	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 17 x 75
6550652000085	Durata Defibrillation Leads	7170Q/52	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 17 x 52
6550652000088	Durata Defibrillation Leads	7170Q/58	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 17 x 58
6550652000091	Durata Defibrillation Leads	7170Q/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 17 x 65
6550652000094	Durata Defibrillation Leads	7171/60	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 21 x 60
6550652000097	Durata Defibrillation Leads	7171/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 21 x 65
6550652000100	Durata Defibrillation Leads	7171/75	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 21 x 75
6550652000103	Durata Defibrillation Leads	7171Q/52	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 21 x 52
6550652000106	Durata Defibrillation Leads	7171Q/58	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 21 x 58
6550652000109	Durata Defibrillation Leads	7171Q/65	ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION (USA) 15900 Valley View Court SYLMAR California USA 91342	True Bipolar x Passive x Dual, 21 x 65



Handwritten signature and stamp, likely indicating approval or verification of the data.

Date 1 August 2022

Letter of Authorization of Distributor
Thailand

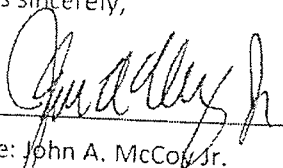
To Whom It May Concern:

This is to certify that St. Jude Medical, LLC ("St. Jude Medical"), having a location at One St. Jude Medical Drive, St. Paul, Minnesota, 55117, USA, authorizes its affiliate, Abbott Medical (Thailand) Co., Ltd (previously known as "St. Jude Medical (Thailand) Co. Ltd."), located at Rasa Tower II, 17th Floor, Unit 1704, 555 Phaholyothin Road, Kwang Chatuchak, Chatuchak, Bangkok 10900, in Thailand, to distribute products of St. Jude Medical in Thailand until further notice.

As such, Abbott Medical (Thailand) Co., Ltd, is authorized to undertake the necessary actions to participate in all auctions and tenders regarding the supply of medical equipment and products from any of the divisions of St. Jude Medical identified above, and, in connection with such activity, to conclude contracts for the supply of such products, to carry out deliveries according to the conditions stipulated in the contracts and tender offers, to appoint sub-distributors to distribute such products in Thailand, and also to carry out any maintenance service, training of staff and to fulfill guarantee obligation, as needed and appropriate.

St. Jude Medical's authorization is valid for all the product lines of the St. Jude Medical Divisions until St. Jude Medical provides further written notification confirming that the services of Abbott Medical (Thailand) Co., Ltd. for the above matters are no longer needed.

Yours sincerely,

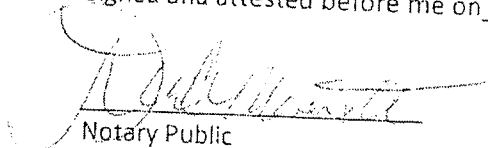
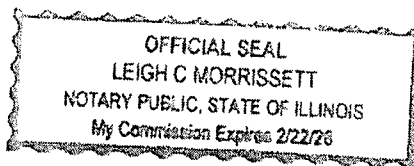


Name: John A. McCoy Jr.

Position: Vice President and Treasurer

STATE OF ILLINOIS
COUNTRY OF LAKE

Signed and attested before me on 1 August, 2022 by John McCoy Jr.


Notary Public

Notary Seal:



เลIGH MORRISSETT

1 สิงหาคม 2565

หนังสืออนุมัติตัวแทนจำหน่าย
ประเทศไทย

เรียน ท่านผู้ที่เกี่ยวข้อง

จดหมายฉบับนี้เพื่อรับทราบว่าบริษัท เซนต์จูด เมดิคัล จำกัด (St. Jude Medical, LLC) (ต่อไปนี้จะเรียกว่า "เซนต์จูด เมดิคัล") ซึ่งมี
สำนักงานตั้งอยู่ที่เลขที่ 1111 เซนต์จูด เมดิคัล ไรโรฟ, เซนต์หลุยส์, รัฐมิสซูรี 63103 ประเทศสหรัฐอเมริกา โดยอนุมัติให้บริษัท ไทยเซนต์
จูด เมดิคัล จำกัด (ประเทศไทย) จำกัด (เรียกเต็มทีชื่อว่า "บริษัท เซนต์จูด เมดิคัล (ประเทศไทย) จำกัด") ที่ตั้งอยู่ที่
เลขที่ 555 ถนนพหลโยธิน ชั้น 14 ห้องเลขที่ 1704 ถนนพหลโยธิน แขวงจตุจักร เขตจตุจักร กรุงเทพมหานคร 10900 ประเทศไทย ทำการ
จัดจำหน่ายผลิตภัณฑ์เซนต์จูด เมดิคัล ในประเทศไทย จนกว่าจะมีประกาศแจ้งเพิ่มเติม

ด้วยเหตุนี้ บริษัท ไทยเซนต์จูด เมดิคัล (ประเทศไทย) จำกัด จึงได้รับอนุมัติให้ดำเนินการต่างๆ ที่จำเป็นเพื่อเข้าร่วมในการประมูล
และการประกวดราคาใดๆ ทั้งหมดเกี่ยวกับการจัดซื้ออุปกรณ์และผลิตภัณฑ์ทางการแพทย์จากแบบใดๆ ของเซนต์จูด เมดิคัล (สหรัฐ
อเมริกา) ขึ้นมา ทำการสรุปสัญญาในการจัดซื้อผลิตภัณฑ์ดังกล่าวโดยที่บริษัทต้องปฏิบัติตามเงื่อนไขการประมูลดังกล่าว ดำเนินการส่งมอบตาม
เงื่อนไขที่ระบุไว้ในสัญญาและการประกวดราคา, บริษัทตัวแทนจำหน่ายซึ่งเพื่อจัดจำหน่ายผลิตภัณฑ์ดังกล่าวในประเทศไทย และ
ให้บริการทางการแพทย์ในต่างประเทศ, ดำเนินการฝึกอบรมพนักงาน และปฏิบัติตามข้อกำหนดด้านการศึกษา ฝึกอบรม และพัฒนา
การปฏิบัติงานของผลิตภัณฑ์เซนต์จูด เมดิคัลที่มีผลกับกลุ่มผลิตภัณฑ์ทั้งหมดของแบบต่างๆ ของเซนต์จูด เมดิคัล (สหรัฐ
อเมริกา) จะมีประกาศแจ้งเพิ่มเติม เพื่อยืนยันว่าบริการต่างๆ ของบริษัท ไทยเซนต์จูด เมดิคัล (ประเทศไทย) จำกัด สัมพันธ์กับการดำเนินการ
ข้างต้นนี้จะมีผลบังคับใช้ต่อไป

ขอแสดงความนับถือ

(ลายมือชื่อ)

จอห์น แล็คคอกซ์ รูเนียร์

รองประธานและเจ้าหน้าที่

รัฐอิลลินอยส์
คิงส์ซี ออฟ เซล

จดหมายและประทับตราส่งมาซึ่งเจ้าหน้าที่วันที่ 1 สิงหาคม 2565 โดยจอห์น แล็คคอกซ์ รูเนียร์

(ลายมือชื่อ)

รับรองขอเช่า

ตราประทับ

ตราประทับที่เป็นลาย
เซ็นชื่อของจอห์น
การรับรองขอเช่า รัฐอิลลินอยส์
ใบอนุญาตเลขที่ 2/22/2569

Pm
สำนักงาน

บริษัท ไทยเซนต์จูด เมดิคัล จำกัด
เลขที่ 555 ถนนพหลโยธิน
จตุจักร กรุงเทพฯ 10900
วันที่ 5 ส.ค. 2565

บริษัท แอ็บบอต เมดิคัล (ประเทศไทย) จำกัด

Abbott Medical (Thailand) Co., Ltd.

สาขา สำนักงานใหญ่

เลขประจำตัวผู้เสียภาษี 0105547136181

ที่อยู่ อาคาร รสา ทาวเวอร์ 2 ชั้น 17 ยูนิต 1704

เลขที่ 555 ถ.พหลโยธิน แขวงจตุจักร เขตจตุจักร กรุงเทพมหานคร 10900

โทรศัพท์ 02-796-6555

โทรสาร 02-937-1148

เลขที่บัญชี : 0031624011

ธนาคาร : ธนาคารแห่งอเมริกา เนชั่นแนล แอสโซซิเอชั่น

Bank of America, N.A.

สาขา : กรุงเทพมหานคร

ประเภทบัญชี : กระแสรายวัน

Beneficiary Name : Abbott Medical (Thailand) Co., Ltd.

Beneficiary Bank : Bank of America, N.A.

Bank Account Number : 0031624011

Swift Code : BOFATH2X

Bank Address : All Seasons Place CRC TWR 33-F
87-2 Wireless Road, Bangkok, Thailand

Bank of America

ACCOUNT NUMBER: 31624011

Bank of America, N.A.

Incorporated in USA with Limited Liability

Branch BIC: BOFATH2X

Branch name/no: BANGKOK BRANCH

6204

Branch address: 87/2 WIRELESS ROAD, PATHUMWAN, BANGKOK, THAILAND

หากมีการโอนชำระค่าสินค้า กรุณาแจ้งที่ email : info.th@abbott.com

