Digitally signed by Ceaicovschi Tudor
Date: 2023.09.29 09:36:36 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ..... din .....

Solicitantul SANTE DISTRIBUȚIE S.R.L., cu sediul Strada Stefan cel Mare, nr. 70B, Straseni, Republica Moldova, tel./fax: +373 795 25 562, e-mail lilicalancea@yahoo.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Swartz Braided Transseptal Guiding Introducers - 407451

Se anexează următoarele acte:

- Lista dispozitivelor medicale solicitate spre notificare
- Împuternicire de la producător
- Declarație pe propria răspundere
- Declaratie de conformitate
- EC Certificate
- Regulatory Letter

Data 29.09.23

REPUBLICA MOLDOVA MUN. STRĂȘENI «SANTE DISTRIBUȚIE» S.R.L. IDNO 1014600040477 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Semnătura

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

REPUBLICA MOLDOVA or. STRĂȘENI «SANTE DISTRIBUȚIE» S.R.L. IDNO 1014600040477 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SJM Coordination Center BV
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
Main +32 2 774 68 11
Fax +32 2 772 83 84

February 28, 2023

To Whom It May Concern

We, St. Jude Medical Coordination Center BV (hereinafter referred to as "Abbott") with its principal place of business at Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium, hereby confirm that the company:

SANTE INTERNATIONAL S.A.,
7 Mihai Bravu boulevard, 1st floor, ap.4, District 2,
Bucharest, Romania

is Abbott's Distributor for the territory of Romania and Republic of Moldova, as specified in the Distribution Agreement dated 1 January 2023, and as such authorized to import, commercialize and deliver Structural Heart products manufactured by St. Jude Medical (Abbott Medical).

The Distributor is authorized to obtain and maintain in effect all necessary registration permits, licenses and approvals in accordance with local applicable laws and regulations required for the importation of Products into, and the distribution, sale, resale, and use of products within the Territory of Romania and Republic of Moldova.

With regards to the Republic of Moldova, this authorization extends to Sante Distributie SRL, MD-3701, 70b, Stefan cel Mare Str., Straseni, Republic of Moldova.

Unless revoked earlier in writing by SJM, this Letter of Authorization shall remain valid until 31 December 2023.

Yours faithfully,

Charbel Mouawad
General Manager – Structural Heart Emerging Markets

ST. JUDE MEDICAL
ST. JUDE MEDICAL COORDINATION CENTER
The Corporate Village
Avenue Da Vincilaan 11 - Box F1
B-1935 Zaventem
Tel. +32 2 774 68 11 - Fax +32 2 772 83 84

REPUBLICA MOLDOVA or. STRASENI "SANTE DISTRIBUTIE" S.R.L. IDNO 1014600040477 SOCIETATEA CU RASPUNDERE LIMITATA

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
Main +32 2 774 68 11
Fax +32 2 772 83 84

February 13, 2019

To whom it may concern

St. Jude Medical Coordination Center BVBA, located at Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium, the EU representative of manufacturer LightLab Imaging Inc. (Abbott Medical) hereby confirms that company Sante International SA, 7 Mihai Bravu Blvd., postal code 021303, Bucharest, Romania is authorized distributor for products manufactured by this manufacturer.

St. Jude Medical companies were acquired by Abbott in 2017 and are now part of Abbott company.

Matthias Koch
Finance Director

REPUBLICA MOLDOVA «SANTE DISTRIBUTIE» S.R.L. IDNO 1014600040471

Traducere din limba engleza

Abbot

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Casuta postala F1
1935 Zaventem, Belgia
Tel: +32 2 774 68 11
Fax: _32 2 772 83 84

13 februarie 2019

IN ATENTIA CELOR INTERESATI,

St. Jude Medical Coordination Center BVBA, cu sediul in Da Vincilaan 11, Box F1, 1935 Zaventem, Belgia, reprezentantul in UE al producatorului LightLab Imaging Inc. (Abbott Medical) confirma prin prezenta ca societatea Sante International S.A., Bd. Mihai Bravu 7, cod postal 021303, Bucuresti, Romania, este distribuitor autorizat pentru produsele fabricate de acest producator.

Societatile St. Jude Medical au fost preluate de catre Abbott in 2017 si acum sunt parte a societatii Abbott.

Semnatura indescifrabila
Matthias Koch
Director Financiar

REPUBLICA MOLDOVA «SANTE DISTRIBUTIE» S.R.L. IDNO 1014600040477

TRADUCATOR AUTORIZAT AL MINISTERULUI DE JUSTITIE
CARAMUZI CRISTINA
Nr. 718
germana, engleza

Enterprise data

In general

Enterprise number:	0888.256.714
Status:	**Active**
Legal situation:	**Normal situation** Since March 26, 2007
Start date:	March 26, 2007
Legal name:	St. Jude Medical Coordination Center Denomination in Dutch, since July 30, 2012
Abbreviation:	SJM Coordination Center Denomination in Dutch, since July 30, 2012
Trade Name:	Abbott Medical Denomination in Dutch, since January 30, 2018
Head office's address:	Da Vincilaan 11 box F1 1930 Zaventem Additional address information: 1935 The Corporate Village Since March 21, 2007
Telephone number:	No data included in CBE
Fax:	No data included in CBE
Email address:	No data included in CBE
Web Address:	No data included in CBE
Enterprise type:	Legal person
Legal form:	Private limited liability company Since March 21, 2007
Number of establishment units (EU):	**2** List EU - information and activities for each establishment unit

Legal functions

Manager	Koch , Matthias	Since May 20, 2014
Manager	OOSTERBAAN , BENJAMIN	Since February 3, 2017
Manager	YOOR , BRIAN	Since February 3, 2017

Proof of professional skills and basic knowledge of enterprise governance

Non SME dispensation Since September 2, 2013	Dispensation Since September 2, 2013

Characteristics

Employer National Social Security Office
Since July 30, 2007

Enterprise liable to VAT
Since April 1, 2007

Commercial company
Since September 2, 2013

Licences

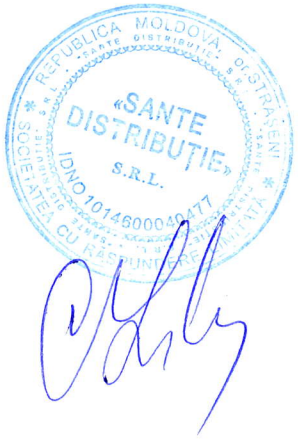
No data included in CBE

Version of the Nacebel codes for the VAT activities 2008*

VAT 2008 70.100 - Activities of head offices
Since August 21, 2009

VAT 2008 46.460 - Wholesale trade of pharmaceutical goods
Since August 21, 2009

VAT 2008 70.220 - Business and other management consultancy activities
Since January 1, 2008



Version of the Nacebel codes for the NOSS activities 2008*

NOSS 2008 70.100 - Activities of head offices
Since April 1, 2008

Show the activities for NACEBEL codification version 2003

Financial information

Authorized capital	374.621.325 EUR
Annual assembly	May
End date financial year	31 December

Links between enterprises

No data included in CBE

External links

Publications National Gazette
Publication of the annual accounts in the Central Balance Sheet Office
Employers directory

(*) The EC-classification of the Nacebel codes has changed on 1/1/2008. Both the Nacebel codification of 2003 and 2008 are available in Public Search. The 2003 codes were valid until 31/12/2007. On 1/1/2008, the new codification became valid. This was a mere administrative conversion : no activities of the enterprise or establishment unit have thus been changed.

Back

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: SANTE DISTRIBUȚIE S.R.L., cu sediul Strada Stefan cel Mare, nr. 70B, Straseni, Republica Moldova,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

Swartz Braided Transseptal Guiding Introducers - 407451

Sunt autentice și corespund realității.

Numele, prenumele și funcţia Calaucea Lilia Administrator *Semnătura* _____

Data 29.09.22

REPUBLICA MOLDOVA «SANTE DISTRIBUȚIE» S.R.L. IDNO 1014600040477 RĂSPUNDERE LIMITATĂ

Abbott Declaration of Conformity Swartz Braided Transseptal Guiding Introducers

Abbott Medical (Abbott) hereby declares that the following Abbott facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. All supporting documentation is retained under the premises of Abbott. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	Abbott Medical 5050 Nathan Lane Plymouth, MN 55442 USA
European Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Introducer
Product Name(s):	Swartz Braided Transseptal Guiding Introducer
Model Number(s):	See **Table 1** and **Table 2**
Classification:	Class III, Rule 7 according to Annex IX of the MDD 93/42/EEC as amended by 2007/47/EC
GMDN Code(s):	47247 – Transseptal access system
Original CE Mark Date:	23 Aug 2011
Certificate No and expiration date:	Design Exam Certificate No: CE 701340 Expiration Date: 15 May 2023 Full Quality Assurance Certificate No: CE 701333 Expiration Date: 26 May 2024
Applicable Quality System Standards:	EN ISO 13485:2016
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Kaynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body Number:	2797

Signature:

Blair Schwartz
Sr. Regulatory Affairs Manager

05 Apr 2021
Issue Date

REPUBLICA MOLDOVA «SANTE DISTRIBUȚIE» S.R.L. IDNO 1014600040471 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Abbott Declaration of Conformity Swartz Braided Transseptal Guiding Introducers

Table 1: Swartz Braided Transseptal Guiding Introducers

Reorder Number	Sheath Size (French)	Dilator Size (French)	Maximum Guidewire Dia. (in)	Curve Type	Sheath Usable Length (cm)	Dilator Usable Length (cm)
407439	8	8	0.032	SL1	63	67
407440				SL1	81	85
407441				SL2	63	67
407442				SL2	81	85
407443				SL3	63	67
407445				SLR3	63	67
407446				SL4	63	67
407448				SLR4	63	67
407449				SL0	63	67
407450				SL0	81	85
407451	8.5	8.5		SL0	63	67
407452				SL0	81	85
407453				SL1	63	67
407454				SL1	81	85
407455				SL2	63	67
407456				SL2	81	85
407457				SL3	63	67
407459				SL4	63	67

Table 2: Swartz Braided LAMP Transseptal Guiding Introducers

Reorder Number	Sheath Size (French)	Dilator Size (French)	Maximum Guidewire Dia. (in)	Curve Type	Sheath Usable Length (cm)	Dilator Usable Length (cm)
407356	8	8	0.032	LAMP 90	63	67
407357	8	8			81	85
407358	8.5	8.5			63	67
407359	8.5	8.5			81	85
407360	8	8		LAMP 45	63	67
407362	8.5	8.5			63	67
407363	8.5	8.5			81	85
407364	8	8		LAMP 135	63	67
407365	8	8			81	85
407366	8.5	8.5			63	67
407367	8.5	8.5			81	85

Signature:

Blair Schwartz
Sr. Regulatory Affairs Manager

05 Apr 2021
Issue Date

REPUBLICA MOLDOVA, O. STRĂȘENI, «SANTE DISTRIBUȚIE» S.R.L. IDNO 1014600004771 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

bsi.

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 701340**

Issued To: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Swartz Braided Transseptal Guiding Introducers

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-12-12** Date: **2019-12-16** Expiry Date: **2023-05-15**

...making excellence a habit.™

REPUBLICA MOLDOVA «SANTE DISTRIBUȚIE» S.R.L. IDNO 1014600040477 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

bsi.

By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 701340

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Swartz Braided Transseptal Guiding Introducers

Model numbers:

407356, 407357, 407358, 407359, 407360, 407362, 407363, 407364, 407365, 407366, 407367, 407439, 407440, 407441, 407442, 407443, 407445, 407446, 407448, 407449, 407450, 407451, 407452, 407453, 407454, 407455, 407456, 407457, 407459

REPUBLICA MOLDOVA «SANTE DISTRIBUȚIE» S.R.L. IDNO 1014600040477 SOCIETATEA CU RĂSPUNDERE LIMITATĂ STRĂȘENI

First Issued: **2018-12-12** Date: **2019-12-16** Expiry Date: **2023-05-15**

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bsi.

By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 701340

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
12 December 2018	9663723	First Issue. Mirror certificate to CE 597706.
05 March 2019	8250541	Traceable to NB 0086.
10 April 2019	9752528	Addition of Sterigenics US, LLC, Salt Lake City, Utah for ETO Sterilization.
Current	3053900	Addition of Midwest Sterilization Corporation, Jackson, Missouri USA for ETO Sterilization in chambers 1, 2, 3, 6, and 13.

First Issued: **2018-12-12** Date: **2019-12-16** Expiry Date: **2023-05-15**

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REPUBLICA MOLDOVA «SANTE DISTRIBUTIE» S.R.L. IDNO 1014600040477 SOCIETATEA CU RASPUNDERE LIMITATA

bsi.

25 Apr 2023

Our ref: Swartz Braided Transseptal Guiding Introducers and Fast-Cath Introducers

To: Whom it may concern

This letter confirms that BSI – Netherlands, an EU Notified Body (designation CE 2797), has issued the following Directive certificates to the Legal Manufacturer Abbott Medical (also known as St. Jude Medical prior acquisition), 5050 Nathan Lane North, Plymouth, MN 55442, USA:

EC Certificate – Full Quality Assurance System – MDD 93/42/EEC Annex II.3		
Certificate	Scope	Expiry
CE 701333	Design, Development, and Manufacture of Electrophysiology Catheters including Radio Frequency (RF) Ablation Electrodes and Catheters, Return Electrodes, Radio Frequency (RF) Ablation Generators, Introducers and Needles, Catheters, Diagnostic Guidewires, Guidewires, and Accessories. Those aspects of Annex II related to securing and maintaining the sterility in the manufacture of Sterile Cables/leads for use with Electrophysiology Catheters, Guidewire Torque Devices, Hemostasis and Compression devices. Those aspects of Annex II related to maintaining the measuring function of FemoStop Pump systems.	26 May 2024
CE 797699 (mirror cert under St. Jude Medical)	Design, Development, and Manufacture of Electrophysiology Catheters including Radio Frequency (RF) Ablation Electrodes and Catheters, Return Electrodes, Introducers and Needles, Catheters, Diagnostic Guidewires, and Accessories. Those aspects of Annex II related to securing and maintaining the sterility in the manufacture of Sterile Cables/leads for use with Electrophysiology Catheters, Hemostasis and Compression devices. Those aspects of Annex II related to maintaining the measuring function of FemoStop Pump systems.	26 May 2024

EC Design-Examination Certificate – Directive 93/42/EEC on Medical Devices, Annex II Section 4		
Certificate	Scope	Expiry
CE 701340 CE 597706 (mirror cert under St. Jude Medical)	Swartz Braided Transseptal Guiding Introducers	15 May 2023

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9, 1066 EP Amsterdam
PO Box 74103, 1070 BC Amsterdam
The Netherlands

T: +31 20 346 0780
BSIMedDev.NB2797@bsigroup.com
bsigroup.com
bsigroup.nl

bsi.

EC Design-Examination Certificate – Directive 93/42/EEC on Medical Devices, Annex II Section 4		
Certificate	Scope	Expiry
CE 701338 CE 597705 (mirror cert under St. Jude Medical)	Fast-Cath Introducers	15 May 2023

BSI confirms that the Legal Manufacturer has applied for MDR certification with BSI including signing an application contract by 26 May 2024 and before the expiration of the Directive certificates.

BSI has issued EU Quality Management System Certificate MDR 728953 under Medical Device Regulation (EU) 2017/745, Annex IX Chapter I and III to the Legal Manufacturer:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

The following devices are covered under MDR 728953 within the device schedule:

EU Quality Management System Certificate, MDR 2017/745 Annex IX Chapter I and III	
Class III device	Intended Purpose
Swartz Braided Transseptal Guiding Introducers	See MDR 759191
Fast-Cath Introducers	See MDR 759190

In addition to the EU Quality Management System MDR 728953, BSI also issued EU Technical Documentation Assessment Certificates for Class III devices. BSI has issued EU Technical Documentation Assessment Certificate MDR 759191 and MDR 759190 under Regulation (EU) 2017/745 Annex IX Chapter II, to the aforementioned Legal Manufacturer in respect of the above devices. Both certificates were first issued on 14 Feb 2023 and valid until 13 Feb 2028.

Should you have any questions regarding this letter or the certificates issued by BSI, please do not hesitate to contact me.

Yours sincerely,

Chase Thompson

REPUBLICA MOLDOVA «SANTE DISTRIBUTIE» S.R.L. IDNO 1014600040477 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Chase.Thompson@bsigroup.com
Technical Team Manager – Vascular
Medical Devices
BSI Group