Therapy™ Ablation Catheters
4 & 8 mm Tip Thermocouple
Quadripolar
7 F

Product Highlights

- Uni-directional steering
- Thermocouple temperature measurement
- Push/pull handle

Ordering Information

7 F ablation catheter (1 unit per box)

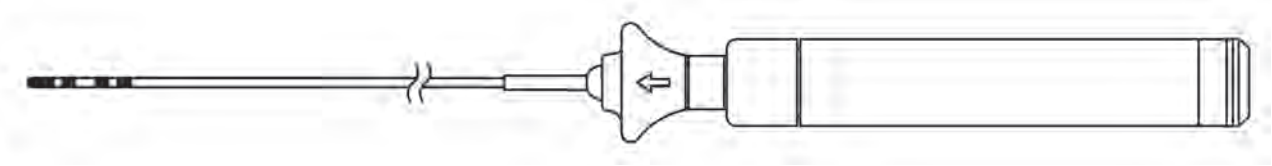
Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type	Usable Length (cm)
83302	1304-7-25-M-TE8	2-5-2	8	2	Medium	110
83306	1304-7-25-L-TE8	2-5-2	8	2	Large	110
83309	1304-7-25-L-TE8A	2-5-2	8	2	Large	110
83311	1304-7-25-XL-TE8A	2-5-2	8	2	X-Large	110
83312	1304-7-25-XL-TE8	2-5-2	8	2	X-Large	110
83404	1304-7-2-M	2	4	2	Medium	110
83405	1304-7-25-M	2-5-2	4	2	Medium	110
83408	1304-7-25-L	2-5-2	4	2	Large	110
83411	1304-7-25-E	2-5-2	4	2	Extended Reach	110
83413	1304-7-2-F	2	4	2	Far Reach	110
83417	1304-7-25-XL	2-5-2	4	2	X-Large	110
83432	1304-7-25-S	2-5-2	4	2	Small	110

Required Catheter Connecting Cable – Page 164

SJM: 85641

Stockert: 85713, 85709

Medtronic: 85711, 85708



ST. JUDE MEDICAL

Therapy™ Ablation Catheters
4 & 8 mm Tip Thermistor
Quadripolar
7 F

Product Highlights

- Uni-directional steering
- Thermistor temperature measurement
- Compatible with EPT-1000 XP generator
- Push/pull handle

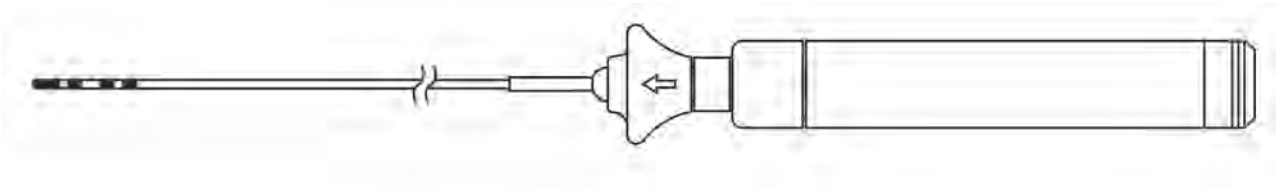
Ordering Information

7 F ablation catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type	Usable Length (cm)
83453	1304-7-25-S-TH	2-5-2	4	2	Small	110
83456	1304-7-25-M-TH	2-5-2	4	2	Medium	110
83459	1304-7-25-L-TH	2-5-2	4	2	Large	110
83462	1304-7-25-XL-TH	2-5-2	4	2	X-Large	110
83477	1304-7-25-L-TE8-TH	2-5-2	8	2	Large	110
83481	1304-7-25-XL-TE8-TH	2-5-2	8	2	X-Large	110

Required Catheter Connecting Cable – Page 164

EPT: 85763



ST. JUDE MEDICAL

EC Design-Examination Certificate

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

No. **CE 65957**

Issued To: **Irvine Biomedical, Inc,**
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA

In respect of:

Therapy™, and Therapy™ Dual-8™ Ablation Catheters using one ablating tip electrode with temperature sensors.

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: **2002-05-27** Date: **2020-10-08** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 65957

Issued To:

Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA

Therapy and Therapy Dual-8 Ablation Catheters

Therapy and Therapy Dual-8 catheter model numbers take the following form, where the parameters are as noted below.

Model No.: 13XX(1)-X(2)-XX(3)-X(4)-XX X(5)-BD(6)

Notes

(1) – Number of electrodes, from 1 to 14

(2) – Outside Diameter in French size, from 5Fr to 9Fr

(3) – Interelectrode spacing, these are variable

(4) – Curve configuration.

(5) – Modification Code (specifies usable length, tip/band electrode length, and the number of temperature sensors

(6) – BD designation will only be present on bi-directional deflection catheters

First Issued: **2002-05-27** Date: **2020-10-08** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 65957

Issued To:

Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA

Catalogue Number	Device Name	Model	Intended purpose per IFU	Classification
IBI-83302	Therapy	1304-7-25-M-TE8	Steerable ablation electrophysiology catheters have been designed for intracardiac recording of complex conduction disturbances as well as for the delivery of radio-frequency energy for therapeutic purposes. The catheters are indicated for use in the treatment of AVNRT, for ablation of accessory pathways, and for the creation of complete AV block in atrial arrhythmias.	Class III
IBI-83306	Therapy	1304-7-25-L-TE8		Class III
IBI-83309	Therapy	1304-7-25-L-TE8A		Class III
IBI-83311	Therapy	1304-7-25-XL-TE8A		Class III
IBI-83312	Therapy	1304-7-25-XL-TE8		Class III
IBI-83351	Therapy	1304-5-25-M-TE4BE1(SOFT)		Class III
IBI-83403	Therapy	1304-5-2-S-TE4BE1		Class III
IBI-83404	Therapy	1304-7-2-M		Class III
IBI-83405	Therapy	1304-7-25-M		Class III
IBI-83408	Therapy	1304-7-25-L		Class III
IBI-83411	Therapy	1304-7-25-E		Class III
IBI-83417	Therapy	1304-7-25-XL		Class III

First Issued: **2002-05-27** Date: **2020-10-08** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 65957

Issued To:

Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA

Catalogue Number	Device Name	Model	Intended purpose per IFU	Classification
IBI-83432	Therapy	1304-7-25-S	Steerable ablation electrophysiology catheters have been designed for intracardiac recording of complex conduction disturbances as well as for the delivery of radio-frequency energy for therapeutic purposes. The catheters are indicated for use in the treatment of AVNRT, for ablation of accessory pathways, and for the creation of complete AV block in atrial arrhythmias.	Class III
IBI-83453	Therapy	1304-7-25-S-TH		Class III
IBI-83456	Therapy	1304-7-25-M-TH		Class III
IBI-83459	Therapy	1304-7-25-L-TH		Class III
IBI-83474	Therapy	1304-7-25-M-TE8-TH		Class III
IBI-83477	Therapy	1304-7-25-L-TE8-TH		Class III
IBI-83481	Therapy	1304-7-25-XL-TE8-TH		Class III
IBI-83510	Therapy	1304-7-25-M-TF		Class III
IBI-83513	Therapy	1304-7-25-S-TF		Class III
IBI-83516	Therapy	1304-7-25-L-TF		Class III
IBI-83552	Therapy	1304-7-25-M-TH-TF (90)		Class III
IBI-83701	Therapy	1304-7-25-M-BD		Class III
IBI-83702	Therapy	1304-7-25-L-BD		Class III
IBI-83703	Therapy	1304-7-25-S-BD		Class III
IBI-83704	Therapy	1304-7-25-L-TE8-BD		Class III

First Issued: **2002-05-27** Date: **2020-10-08** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 65957

Issued To:

Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA

Catalogue Number	Device Name	Model	Intended purpose per IFU	Classification
IBI-83705	Therapy	1304-7-25-XL-BD	Steerable ablation electrophysiology catheters have been designed for intracardiac recording of complex conduction disturbances as well as for the delivery of radio-frequency energy for therapeutic purposes. The catheters are indicated for use in the treatment of AVNRT, for ablation of accessory pathways, and for the creation of complete AV block in atrial arrhythmias.	Class III
IBI-83707	Therapy	1304-7-25-M-TE8-BD		Class III
IBI-83708	Therapy	1304-7-25-XL-TE8-BD		Class III
IBI-83308	Therapy Dual-8	1304-7-25-L-TE8TC2A		Class III
IBI-83422	Therapy Dual-8	1304-7-25-M-TE8TC2		Class III
IBI-83424	Therapy Dual-8	1304-7-2-L-TE8TC2		Class III
IBI-83425	Therapy Dual-8	1304-7-25-L-TE8TC2		Class III
IBI-83428	Therapy Dual-8	1304-7-25-XL-TE8TC2		Class III
IBI-83542	Therapy Dual-8	1304-7-25-L-TE8TC2-TF		Class III
IBI-83543	Therapy Dual-8	1304-7-25-XL-TE8TC2-TF		Class III
IBI-83545	Therapy Dual-8	1304-7-25-M-TE8TC2-TF		Class III

First Issued: **2002-05-27** Date: **2020-10-08** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 65957

Issued To:

Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA

Certificate History

Date	Reference Number	Action
27 May 2002	10035311	Original Issue
30 April 2003	10049544	Modifications to existing device
09 July 2004	10059218	Change of address New certificate format
12 February 2007	10083251 10083250	Name change to include "a St. Jude Medical Company" Therapy™ PLUS Catheters added to the scope
24 April 2007	10087839	Renewal and text change in the scope
04 April 2012	10134047	Certificate renewal
28 March 2014	10145858	Correct certificate to add the Therapy Dual-8 name to the scope
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
25 May 2017	10169587	Certificate Renewal

First Issued: **2002-05-27** Date: **2020-10-08** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 65957

Issued To:

Irvine Biomedical, Inc,
a St. Jude Medical Company
2375 Morse Avenue
Irvine
CA 92614
USA

Certificate History

Date	Reference Number	Action
05 March 2019	7781598	Traceable to NB 0086.
22 April 2020	3100574	Change affecting packaging pouch DuPont Tyvek 1073B packaging material. Addition of product table.
11 May 2020	9767642	Certificate Renewal. Removal of Therapy™ PLUS catheters from scope statement. Removal of all models beginning with "12XX" for Therapy, Therapy Dual-8, and Therapy PLUS ablation catheters without temperature sensors.
Current	3174231	Qualification second sterilization cycle.

First Issued: **2002-05-27** Date: **2020-10-08** Expiry Date: **2024-05-26**

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SJM Declaration of Conformity
Therapy™ and Therapy™ Dual-8™ Ablation Catheters

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of *Annex* II of the Medical Device Directive (MDD) 93/42/EEC, as amended by 2007/42/EC. All supporting documentation is retained under the premises of SJM. 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:
Irvine Biomedical, Inc.
a St. Jude Medical Company
2375 Morse Avenue
Irvine, CA 92614, USA

European Representative:
St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type:
Ablation Catheters

Product Name(s):
Therapy™ Ablation Catheter and Therapy™ Dual-8™ Ablation Catheter

Model No.:
Therapy™ and Therapy™ Dual-8™ Ablation Catheters using one ablation tip electrode with temperature sensors

13XX(1)-X(2)-XX(3)-X(4)-XX X(5)-BD(6)

Notes:
(1) – Number of electrode, from 1 to 14
(2) – Outside Diameter in French size, 5Fr to 9Fr
(3) – Interelectrode spacing, these are variable
(4) – Curve configuration
(5) – Modification Code (specifies usable length, tip/band electrode length, and the number of temperature sensors
(6) – BD designation will only be present on bi-directional deflection catheters

Model	Catalogue Number	Product Name
1304-7-25-M-TE8	IBI-83302	Therapy™ Ablation Catheter
1304-7-25-L-TE8	IBI-83306	
1304-7-25-L-TE8A	IBI-83309	
1304-7-25-XL-TE8A	IBI-83311	
1304-7-25-XL-TE8	IBI-83312	
1304-5-25-M-TE4BE1(SOFT)	IBI-83351	
1304-5-2-S-TE4BE1	IBI-83403	
1304-7-2-M	IBI-83404	
1304-7-25-M	IBI-83405	
1304-7-25-L	IBI-83408	
1304-7-25-E	IBI-83411	
1304-7-25-XL	IBI-83417	
1304-7-25-S	IBI-83432	
1304-7-25-S-TH	IBI-83453	

1304-7-25-M-TH	IBI-83456	
1304-7-25-L-TH	IBI-83459	
1304-7-25-M-TE8-TH	IBI-83474	
1304-7-25-L-TE8-TH	IBI-83477	
1304-7-25-XL-TE8-TH	IBI-83481	
1304-7-25-M-TF	IBI-83510	
1304-7-25-S-TF	IBI-83513	
1304-7-25-L-TF	IBI-83516	
1304-7-25-M-TH-TF(90)	IBI-83552	
1304-7-25-M-BD	IBI-83701	
1304-7-25-L-BD	IBI-83702	
1304-7-25-S-BD	IBI-83703	
1304-7-25-L-TE8-BD	IBI-83704	
1304-7-25-XL-BD	IBI-83705	
1304-7-25-M-TE8-BD	IBI-83707	
1304-7-25-XL-TE8-BD	IBI-83708	
1304-7-25-L-TE8TC2A	IBI-83308	Therapy™ Dual-8™ Ablation Catheter
1304-7-25-M-TE8TC2	IBI-83422	
1304-7-2-L-TE8TC2	IBI-83424	
1304-7-25-L-TE8TC2	IBI-83425	
1304-7-25-XL-TE8TC2	IBI-83428	
1304-7-25-L-TE8TC2-TF	IBI-83542	
1304-7-25-XL-TE8TC2-TF	IBI-83543	
1304-7-25-M-TE8TC2-TF	IBI-83545	

Classification: Class III, Rule 7 according to Annex IX of the MDD 93/42/EEC

GMDN Code(s): 61785

Original CE Mark Date: 27 May 2002

EC Certificate No and expiration date: Certificate No: CE 65957
Expiration Date: 26 May 2024

Applicable Quality System Standards: 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 (Traceable to NB number 0086, BSI Reference 7781598)

Signature:

_____ _____

Legal Manufacturer
Adam Ettl
Manager, Regulatory Affairs

Issue Date

Abbott Medical

2375 Morse Avenue

Irvine

California

92614

USA

11 Jul 2023

Notified Body Confirmation Letter

Reference: EU2023-607/654473

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Abbott Medical
2375 Morse Ave
Irvine
California
92614
USA

SRN Number (if available): US-MF-000014304

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written

agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

ChiaLei Ang

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Therapy and Therapy Dual-8 Ablation Catheters	Class III	N/A	CE 58528, NB# 2797 CE 65957, NB# 2797
ViewFlex XTRA ICE Catheter	Class III	N/A	CE 58528, NB# 2797 CE 561277, NB# 2797
Inquiry Steerable Diagnostic Catheter	Class III	N/A	CE 58528, NB# 2797 CE 69920, NB# 2797
Inquiry AFocus II Diagnostic Catheter	Class III	N/A	CE 58528, NB# 2797 CE 69920, NB# 2797
Cool Point Irrigation Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 58528, NB# 2797
Cool Point Tubing Set	Class IIa	N/A	CE 58528, NB# 2797
Electrophysiology Cables	Class I device placed on the market in sterile condition	N/A	CE 58528, NB# 2797 CE 85222, NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/07/11	Initial issue

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical Costa Rica Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela
Costa Rica

Holds Certificate No: **FM 728657**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping system accessories, transseptal access system, introducer catheters, vascular closure systems; and the design of cardiac mapping system accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-06
Effective Date: 2021-12-14
Latest Revision Date: 2022-03-22
Expiry Date: 2024-12-13

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CERTIFICATE

This is to certify that

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

has implemented and maintains a **Quality Management System**.

Scope:
Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	497269 QM15
Valid from	2021-06-16
Valid until	2024-06-15
Date of certification	2021-06-16

DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Bucatului nr. 11, 020565 Bucharest - Romania

Annex to certificate
Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

Location	Scope
075906 **Sante International SA** **Sos. Mihai Bravu nr. 7, bl. P37-P37A, sector 2** **021303 Bucuresti** **Romania**	Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.
497270 **Sante International SA** **Str. Pupitrului, nr. 81, sect. 3** **033036 Bucuresti** **Romania**	Storage of medical and laboratory equipment, disinfectants, laboratory reagents,cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050285 **Sante International SA** **Calea Ghirodei, nr. 36** **300327 Timisoara** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050284 **Sante International SA** **Calea Dorobantilor, nr. 111** **400609 Cluj-Napoca** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050283 **Sante International SA** **Str. Lascar Catargi, nr. 37** **700107 Iasi** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

This annex (edition:2021-06-16) is only valid in connection with the above-mentioned certificate.