By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 758373 R000

Manufacturer: Abbott Medical

Address:
14901 DeVeau Place
Minnetonka
Minnesota
55345
USA

Single Registration Number: Not available

EU Authorised Representative: Abbott Medical

Address:
The Corporate Village
Da Vincilaan 11 Box F1
1935
Zaventem
Belgium

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

Digitally signed by Ceaicovschi Tudor
Date: 2025.07.07 10:34:45 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

First Issue Date: **2023-02-08**

Current Issue Date: **2024-03-07**

Starting Validity Date: **2024-03-07**

Expiry Date: **2028-02-07**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 758373 R000

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Agilis™ EPI Steerable Introducer Agilis™ NxT Steerable Introducer	See MDR 758375
BRK™ Transseptal Needle	See MDR 758605
Response™ Electrophysiology Catheter Supreme™ Electrophysiology Catheter	See MDR 758646
Livewire™ Steerable Electrophysiology Catheter	See MDR 758655

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 758373 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-02-08	3541351	Issued
2023-08-09	30000652	Supplemented – Addition of Agilis™ EPI Steerable Introducer, Agilis™ NxT Steerable Introducer, Supreme™ Electrophysiology Catheter, Response™ Electrophysiology Catheter.
Current	30072383	Supplemented – Addition of Livewire™ Steerable Electrophysiology Catheter.

First Issue Date: **2023-02-08**

Current Issue Date: **2024-03-07**

Starting Validity Date: **2024-03-07**

Expiry Date: **2028-02-07**

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By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 758605 R000

Manufacturer: Abbott Medical

Address:
14901 DeVeau Place
Minnetonka
Minnesota
55345
USA

Single Registration Number: not available

EU Authorised Representative: Abbott Medical

Address:
The Corporate Village
Da Vincilaan 11 Box F1
1935
Zaventem
Belgium

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-02-08**

Current Issue Date: **2024-02-22**

Starting Validity Date: **2024-02-22**

Expiry Date: **2028-02-07**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 758605 R000

Device Schedule:

Device Name: BRK™ Transseptal Needle

Intended Purpose as per the Instructions for Use:

The BRK™ Transseptal Needle is intended to be used to puncture the interatrial septum to gain left heart access.

Risk Classification: Class III

Type (Codes as per (EU) 2017/2185): MDN 1203

Basic UDI-DI: 5414734ACS0002C2

Model	Product Description	Gauge Size	Length	Bevel angle
407200	BRK™ Transseptal Needle	18 ga	71 cm	50º
407201	BRK-1™ Transseptal Needle	18 ga	71 cm	50º
407205	BRK™ Transseptal Needle	18 ga	89 cm	50º
407206	BRK™ Transseptal Needle	18 ga	98 cm	50º
407207	BRK-1™ Transseptal Needle	18 ga	98 cm	50º
G407208	BRK™ XS Transseptal Needle	18 ga	71 cm	30º
G407209	BRK-1™ XS Transseptal Needle	18 ga	71 cm	30º
G407210	BRK™ XS Transseptal Needle	18 ga	89 cm	30º
G407211	BRK™ XS Transseptal Needle	18 ga	98 cm	30º
G407212	BRK-1™ XS Transseptal Needle	18 ga	98 cm	30º
G407215	BRK-1™ Transseptal Needle	18 ga	89 cm	50º
G407216	BRK-1™ XS Transseptal Needle	18 ga	89 cm	30º

First Issue Date: **2023-02-08**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 758605 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-02-08	3552126	Issued
2023-11-29	30000590	Amended - Addition of 2 sterilization chambers (#6 and #7) at existing Critical Subcontractor for EO sterilization. Administrative update to add the word "Needle" to the product description for model 407201.
Current	30012179	Amended - Addition of an alternative ETO sterilization site.

First Issue Date: **2023-02-08**

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USA
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00135864 Rev. A
Declaration of Conformity

EU Declaration of Conformity

Manufacturer:	Abbott Medical
Manufacturer SRN:	Not Available
Address:	14901 DeVeau Place Minnetonka MN 55345 USA
Manufacturing Site(s):	Abbott Medical Costa Rica Ltda Edificio #44 Calle 0, Ave. 2, Zona Franca Coyol El Coyol, Alajuela Costa Rica
European Authorized Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Device Name:	BRK™ Transseptal Needle
Product Trade Name(s):	BRK™ Transseptal Needle BRK-1™ Transseptal Needle BRK™ XS Transseptal Needle BRK-1™ XS Transseptal Needle
Model Number(s):	407200; 407201; 407205; 407206; 407207; G407208; G407209; G407210; G407211; G407212; G407215; G407216
Intended Purpose:	The BRK™ Transseptal Needle is intended to be used to puncture the interatrial septum to gain left heart access.
Risk Classification:	Class III invasive device per Rule 7 Annex VIII, Chapter III, Section 5 of the Regulation (EU) 2017/745.

Signature: *Blair Schwartz; Associate Regulatory Affairs Director*	13 July 2023 Issue Date On behalf of Abbott Medical, signed at Plymouth, MN

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EU Declaration of Conformity

Risk Classification Rationale:	BRK™ Transseptal Needle is a short-term use device per Annex VIII, Chapter I, Section 1 of the Regulation (EU) 2017/745. BRK™ Transseptal Needle is non-active surgically invasive device per Annex VIII, Chapter I, Section 2, Sub part 2.2(a) and 2.5 of the Regulation (EU) 2017/745. BRK™ Transseptal Needles are *intended specifically for use in direct contact with the heart or central circulatory system, in which case they are classified as class III;* Per Rule 7, subpart 2 of the (EU)Regulation 2017/745 Annex VIII, Chapter III Section 5.
EMDN Code(s):	C019015 - Cardiovascular System, Cardiac Transseptal Puncture
GMDN Code:	47248, Transseptal Needle
Basic UDI-DI:	5414734ACS0002C2

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

Common Specifications Applied:	N/A
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands NB number 2797
Supporting Certificate(s):	Quality Management System No: MDR 758373 Expiration Date: 2028-02-07 Technical Documentation Assessment No: MDR 758605 Expiration Date: 2028-02-07
Original CE Mark Date:	2023-02-08
Conformity Assessment:	Annex IX of the (EU) Regulation 2017/745

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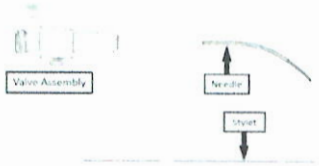
00135864 Rev. A
Declaration of Conformity

EU Declaration of Conformity

Device Photograph:	

The products in the attached Declaration of Conformity Product List are approved under the Technical Documentation Assessment Certificate MDR 758605.

Declaration of Conformity Product List

Model No.	Description	Unique Device Identifier (UDI-DI) GTIN
407200	BRK™ Transseptal Needle	05414734205092
407201	BRK-1™ Transseptal Needle	05414734205160
407205	BRK™ Transseptal Needle	05414734205115
407206	BRK™ Transseptal Needle	05414734205122
407207	BRK-1™ Transseptal Needle	05414734205177
G407208	BRK™ XS Transseptal Needle	05414734205139
G407209	BRK-1™ XS Transseptal Needle	05414734205184
G407210	BRK™ XS Transseptal Needle	05414734205146
G407211	BRK™ XS Transseptal Needle	05414734205153
G407212	BRK-1™ XS Transseptal Needle	05414734205191
G407215	BRK-1™ Transseptal Needle	05414734207225
G407216	BRK-1™ XS Transseptal Needle	05414734207232

The signature is applied on page 1
88136 MDR Declaration of Conformity Template Rev H

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