

# EU Technical Documentation Assessment Certificate

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

## MDR 762879 R000

**Manufacturer:** Abbott Medical

**Address:**

3200 Lakeside Drive  
Santa Clara  
California  
95054  
USA

**Single Registration Number:** US-MF-000003851

**EU Authorised Representative:** Abbott Vascular International BVBA

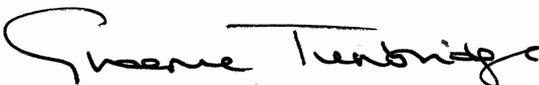
**Address:**

Park Lane, Culliganlaan 2B  
1831 Diegem  
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: **2023-04-19**

Current Issue Date: **2023-04-19**

Starting Validity Date: **2023-04-19**

Expiry Date: **2028-04-18**

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# EU Technical Documentation Assessment Certificate

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

## MDR 762879 R000

**Device Schedule:**

**Device Name:** MINI TREK RX Coronary Dilatation Catheter

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

**Intended Purpose as per the Instructions for Use:** The semi-compliant RX Coronary Dilatation Catheter is intended to dilate the stenotic structures of a coronary artery or bypass graft for the purpose of improving myocardial blood flow/perfusion.

**Risk Classification:** Class III

**Basic UDI-DI:** 8717648CDC0001LW

Model #	Description (balloon diameter, Balloon length)
1012268-06	1.20mm, 6mm
1012268-08	1.20mm, 8mm
1012268-12	1.20mm, 12mm
1012268-15	1.20mm, 15mm
1012268-20	1.20mm, 20mm
1012269-06	1.50mm, 6mm
1012269-08	1.50mm, 8mm
1012269-12	1.50mm, 12mm
1012269-15	1.50mm, 15mm
1012269-20	1.50mm, 20mm
1012270-06	2.00mm, 6mm
1012270-08	2.00mm, 8mm
1012270-12	2.00mm, 12mm
1012270-15	2.00mm, 15mm
1012270-20	2.00mm, 20mm
1012270-25	2.00mm, 25mm
1012270-30	2.00mm, 30mm

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## MDR 762879 R000

**Device Name:** TREK RX Coronary Dilatation Catheter

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

**Intended Purpose as per the Instructions for Use:** The semi-compliant RX Coronary Dilatation Catheter is intended to dilate the stenotic structures of a coronary artery or bypass graft for the purpose of improving myocardial blood flow/perfusion.

**Risk Classification:** Class III

**Basic UDI-DI:** 8717648CDC0001LW

Model #	Description (balloon diameter, Balloon length)
1012271-06	2.25mm, 6mm
1012271-08	2.25mm, 8mm
1012271-12	2.25mm, 12mm
1012271-15	2.25mm, 15mm
1012271-20	2.25mm, 20mm
1012271-25	2.25mm, 25mm
1012271-30	2.25mm, 30mm
1012272-06	2.50mm, 6mm
1012272-08	2.50mm, 8mm
1012272-12	2.50mm, 12mm
1012272-15	2.50mm, 15mm
1012272-20	2.50mm, 20mm
1012272-25	2.50mm, 25mm
1012272-30	2.50mm, 30mm
1012273-06	2.75mm, 6mm
1012273-08	2.75mm, 8mm
1012273-12	2.75mm, 12mm
1012273-15	2.75mm, 15mm
1012273-20	2.75mm, 20mm
1012273-25	2.75mm, 25mm
1012273-30	2.75mm, 30mm

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## MDR 762879 R000

Model #	Description (balloon diameter, Balloon length)
1012274-06	3.00mm, 6mm
1012274-08	3.00mm, 8mm
1012274-12	3.00mm, 12mm
1012274-15	3.00mm, 15mm
1012274-20	3.00mm, 20mm
1012274-25	3.00mm, 25mm
1012274-30	3.00mm, 30mm
1012275-06	3.25mm, 6mm
1012275-08	3.25mm, 8mm
1012275-12	3.25mm, 12mm
1012275-15	3.25mm, 15mm
1012275-20	3.25mm, 20mm
1012275-25	3.25mm, 25mm
1012275-30	3.25mm, 30mm
1012276-06	3.50mm, 6mm
1012276-08	3.50mm, 8mm
1012276-12	3.50mm, 12mm
1012276-15	3.50mm, 15mm
1012276-20	3.50mm, 20mm
1012276-25	3.50mm, 25mm
1012276-30	3.50mm, 30mm
1012277-06	3.75mm, 6mm
1012277-08	3.75mm, 8mm
1012277-12	3.75mm, 12mm
1012277-15	3.75mm, 15mm
1012277-20	3.75mm, 20mm

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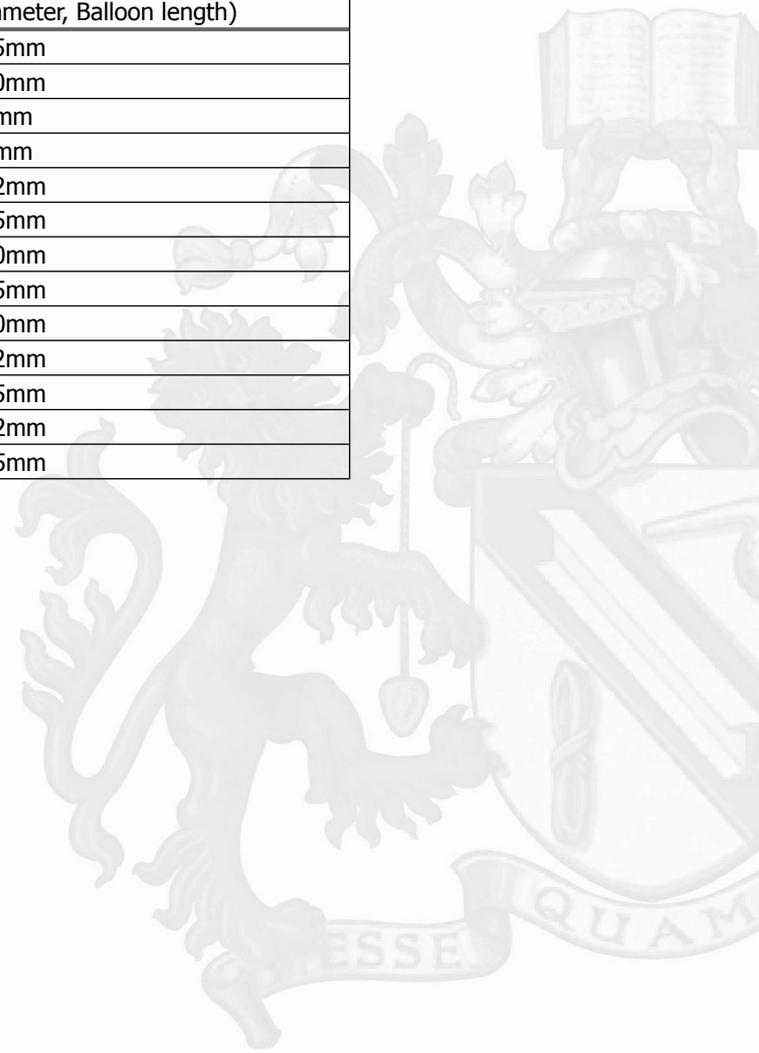
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## MDR 762879 R000

Model #	Description (balloon diameter, Balloon length)
1012277-25	3.75mm, 25mm
1012277-30	3.75mm, 30mm
1012278-06	4.00mm, 6mm
1012278-08	4.00mm, 8mm
1012278-12	4.00mm, 12mm
1012278-15	4.00mm, 15mm
1012278-20	4.00mm, 20mm
1012278-25	4.00mm, 25mm
1012278-30	4.00mm, 30mm
1012279-12	4.50mm, 12mm
1012279-15	4.50mm, 15mm
1012280-12	5.00mm, 12mm
1012280-15	5.00mm, 15mm



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

# EU Technical Documentation Assessment Certificate

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**Device Name:** TRAVELER Coronary Dilatation Catheter

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

**Intended Purpose as per the Instructions for Use:** The TRAVELER semi-compliant RX Coronary Dilatation Catheter is intended to dilate the stenotic structures of a coronary artery or bypass graft for the purpose of improving myocardial blood flow/perfusion.

**Risk Classification:** Class III

**Basic UDI-DI:** 8717648CDC0001LW

Model #	Description (balloon diameter, Balloon length)
1013063-06	1.20mm, 6mm
1013063-08	1.20mm, 8mm
1013063-12	1.20mm, 12mm
1013063-15	1.20mm, 15mm
1013063-20	1.20mm, 20mm
1013064-06	1.50mm, 6mm
1013064-08	1.50mm, 8mm
1013064-12	1.50mm, 12mm
1013064-15	1.50mm, 15mm
1013064-20	1.50mm, 20mm
1013065-06	2.00mm, 6mm
1013065-08	2.00mm, 8mm
1013065-12	2.00mm, 12mm
1013065-15	2.00mm, 15mm
1013065-20	2.00mm, 20mm
1013065-25	2.00mm, 25mm
1013065-30	2.00mm, 30mm
1013066-06	2.25mm, 6mm
1013066-08	2.25mm, 8mm
1013066-12	2.25mm, 12mm

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Model #	Description (balloon diameter, Balloon length)
1013066-15	2.25mm, 15mm
1013066-20	2.25mm, 20mm
1013066-25	2.25mm, 25mm
1013066-30	2.25mm, 30mm
1013067-06	2.50mm, 6mm
1013067-08	2.50mm, 8mm
1013067-12	2.50mm, 12mm
1013067-15	2.50mm, 15mm
1013067-20	2.50mm, 20mm
1013067-25	2.50mm, 25mm
1013067-30	2.50mm, 30mm
1013068-06	2.75mm, 6mm
1013068-08	2.75mm, 8mm
1013068-12	2.75mm, 12mm
1013068-15	2.75mm, 15mm
1013068-20	2.75mm, 20mm
1013068-25	2.75mm, 25mm
1013068-30	2.75mm, 30mm
1013069-06	3.00mm, 6mm
1013069-08	3.00mm, 8mm
1013069-12	3.00mm, 12mm
1013069-15	3.00mm, 15mm
1013069-20	3.00mm, 20mm
1013069-25	3.00mm, 25mm
1013069-30	3.00mm, 30mm
1013070-06	3.25mm, 6mm

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Model #	Description (balloon diameter, Balloon length)
1013070-08	3.25mm, 8mm
1013070-12	3.25mm, 12mm
1013070-15	3.25mm, 15mm
1013070-20	3.25mm, 20mm
1013070-25	3.25mm, 25mm
1013070-30	3.25mm, 30mm
1013071-06	3.50mm, 6mm
1013071-08	3.50mm, 8mm
1013071-12	3.50mm, 12mm
1013071-15	3.50mm, 15mm
1013071-20	3.50mm, 20mm
1013071-25	3.50mm, 25mm
1013071-30	3.50mm, 30mm
1013072-06	3.75mm, 6mm
1013072-08	3.75mm, 8mm
1013072-12	3.75mm, 12mm
1013072-15	3.75mm, 15mm
1013072-20	3.75mm, 20mm
1013072-25	3.75mm, 25mm
1013072-30	3.75mm, 30mm
1013073-06	4.00mm, 6mm
1013073-08	4.00mm, 8mm
1013073-12	4.00mm, 12mm
1013073-15	4.00mm, 15mm
1013073-20	4.00mm, 20mm
1013073-25	4.00mm, 25mm

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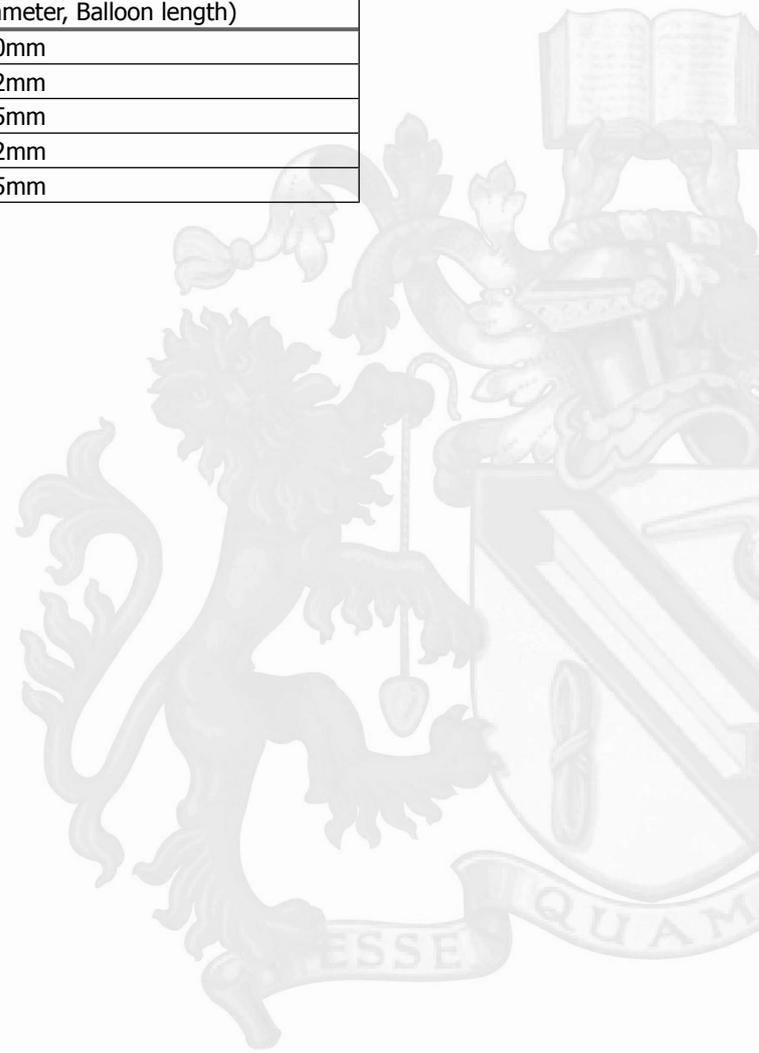
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Model #	Description (balloon diameter, Balloon length)
1013073-30	4.00mm, 30mm
1013074-12	4.50mm, 12mm
1013074-15	4.50mm, 15mm
1013075-12	5.00mm, 12mm
1013075-15	5.00mm, 15mm



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### 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
Current	3586886	Issued.



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