ID	Information Sheet	Revision Date	Rev. #
IS4507	SSCP	05/09/2023	03

An SSCP is part of the CER and will therefore be an attachment to a CER.
Consequently the SSCP approval will be approved via the CER approval.
This first page is for or own QMS documentation and should be removed for public release of the SSCP.

SSCP

Summary of Safety and Clinical Performance

Summit

Attachment 5 – TFC.1602.14

Date: 08 August 2024

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Dy. Manager Regulatory Affairs

TITLE: TF5.1608.05 SSCP_Summit semi-compliant_PTCA

SSCP

Summary of Safety and Clinical Performance

Summit CTO PTCA balloon dilatation catheter

Basic UDI-DI: 872063420BMD-PTCAJ

To be completed upon final NB approval		Signature	Date
Prepared by	Richa Rohilla		
Reviewed by	Alex Luijkx		
Approved by	Dr. Brijesh Mishra		
	Dr. Nancy Chugh		

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Summary of safety and clinical performance

Intended for health care professionals

1 Device identification and general information

1.1 Device trade name

The scope of this SSCP are the following medical device:
Device trade name : Summit

1.2 Manufacturer's name and address

The manufacturer of the semi-compliant (SC) Summit CTO PTCA balloon dilatation catheter is:

Name	: Blue Medical Devices B.V.
Person Responsible for Regulatory Compliance	: Alex Luijkx
Contact person	: Alex Luijkx
Visiting address	: Panovenweg 7
Postal code	: 5708 HR
City	: Helmond
Country	: The Netherlands
Phone	: +31(0)492 588 900
Website	: www.translumina.com

1.3 Manufacturer's SRN

The manufacturer's Single Registration Number is:
SRN : NL-MF-000002976

1.4 Basic UDI-DI

The basic-UDI DI of the Summit CTO PTCA catheter is

	Summit
Basic UDI-DI	872063420BMD-PTCAJ9 Summit: SUMxxxx01

1.5 Medical Device Nomenclature description / text

The Summit CTO PTCA catheter medical device nomenclature code used is:
Medical device Nomenclature code : UMDNS 17521
This code applies to Catheters, Angioplasty Balloon dilatation, Coronary Perfusing.

Device group CND: Cardiac angiography device
The CND/EMDN code of the device is C010401020101 describing: Angioplasty catheters, balloon dilatation, coronary/PTCA Balloon dilation Catheter.

1.6 Class of device

By application of the classification rules in Annex VIII of the Medical Device Regulations MDR 2017/745 Blue Medical Devices B.V. Summit CTO PTCA balloon dilatation catheter is a Class III medical device according

- rule 6 (described as surgically invasive device for transient/impermanent use), as the device is intended for use in direct contact with the heart or central circulatory system.

1.7 Year when the first certificate (CE) was issued covering the device

The first approval for CE under the MDD 93/42/EEC was obtained for Summit CTO PTCA balloon dilatation catheter in 2008.

1.8 Notified body name and single identification number

Name Notified body : British Standards Institute (BSI)
Single identification number : 2797

2 Intended use of the device

2.1 Intended purpose

The SC PTCA balloon catheter (Summit) is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial reperfusion in patients requiring a percutaneous coronary interventional (PCI) procedure in a blood vessel.
The SC PTCA balloon catheter (Summit) is intended for transient use (≤60 minutes).

2.2 Indication(s) and target population(s)

The SC PTCA balloon catheter (Summit) is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial reperfusion.

2.3 Contraindications and/or limitations

The Summit CTO PTCA balloon dilatation catheter is contraindicated for

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a significant stenosis

3 Device description

3.1 Description of the device

The Blue Medical Devices B.V. PTCA balloon dilatation catheter, Summit, is a rapid exchange (Rx) catheter with a semi-compliant (SC) balloon near the distal tip. The distal section of the outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 inch (0.36 mm) to facilitate advancement of the catheter through blood vessels, to and through the stenosis or stent to be dilated. The proximal section of the catheter is a single-lumen, stainless steel Hypotube with a single luer port hub for inflation/deflation of the balloon. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The PTCA balloon catheter is supplied with a balloon protector placed over the balloon to maintain a low profile and an eyed stylet is placed into the inner lumen to protect the patency of the catheter. The catheter tip is tapered to facilitate advancement of the catheter to and through a stenosis or stent. The shaft has a hydrophilic coating.
All variants of Summit CTO PTCA balloon dilatation catheter with their Basic UDI-DI identified in section 1.4 are presented in
Table 1 below, with model (product family) name and UDI-DI number.

Device trade name : Summit

Table 1: Basic UDI-DI and UDI-DI for all variants (sizes) of the Summit

Product family	Balloon diameter (mm)	Balloon length (mm)	Rev #	Basic UDI-DI	UDI-DI
SUMMIT	1.1	10	01	872063420BMD-PTCAJ9	SUM111001
SUMMIT	1.1	15	01	872063420BMD-PTCAJ9	SUM111501
SUMMIT	1.1	20	01	872063420BMD-PTCAJ9	SUM112001
SUMMIT	1.25	10	01	872063420BMD-PTCAJ9	SUM121001
SUMMIT	1.25	15	01	872063420BMD-PTCAJ9	SUM121501
SUMMIT	1.25	20	01	872063420BMD-PTCAJ9	SUM122001
SUMMIT	1.5	10	01	872063420BMD-PTCAJ9	SUM151001
SUMMIT	1.5	15	01	872063420BMD-PTCAJ9	SUM151501

SUMMIT	1.5	20	01	872063420BMD-PTCAJ9	SUM152001

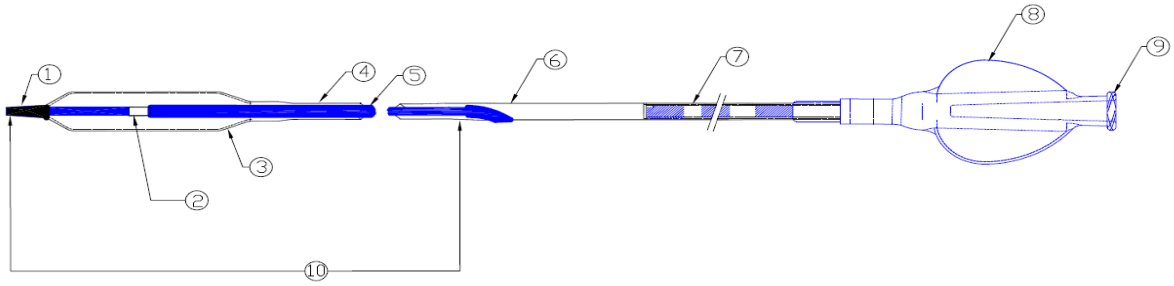
3.1.1 Principles of operation

The Summit CTO PTCA balloon dilatation catheter is advanced through the vasculature over a routinely used 0.014" guidewire. Under high quality fluoroscopic guidance, the catheter is advanced until the PTCA balloon is positioned at the required location in the target lesion. The balloon is inflated (using standard coronary interventional technique by means of an inflation device) and the lesion dilated. The deflated balloon catheter is withdrawn.

3.1.2 Key functional elements

A schematic representation of the rapid exchange Summit CTO PTCA balloon dilatation catheter with indicated key functional elements is shown in *Figure 1*.

Figure 1: *Schematic representation of the rapid exchange Summit CTO PTCA balloon dilatation catheter, with key functional elements indicated*



No.	Functional element	No.	Functional element
1	Soft tip	6	Intermediate shaft
2	Radiopaque Marker Bands	7	Hypotube
3	Balloon	8	Hub with Strain Relief
4	Outer Body / Distal shaft	9	Luer Hub Lock
5	Inner Body	10	Hydrophilic Coating

3.1.3 Materials in direct contact

Materials that come in direct contact with the patient (blood, heart vasculature, central circulating system) are:

- PTFE *Hypotube*
- Pebax *Outerbody, Intermediate Shaft, Soft-tip (tip tubing)*
- Pebax and HDPE *Innerbody*
- Polyamide composite material *Balloon material*
- Hydrophilic coating

Materials that come in indirect contact with the patient are:

- PI/IR marker
- Luer Hub Lock

The contact duration of the materials is ≤60 minutes.
Sterilization of the device is with EtO.

3.1.4 Special design attributes

3.1.4.1 Medicinal substances

Blue Medical Devices B.V. states that Summit CTO PTCA balloon dilatation catheter does not incorporate a medicinal substance.

3.1.4.2 Components of biological origin

Blue Medical Devices B.V. states that Summit CTO PTCA balloon dilatation catheter does not incorporate viable materials of animal origin.

3.1.4.3 Components of human origin

Blue Medical Devices B.V. states that Summit CTO PTCA balloon dilatation catheter does not incorporate tissues and/or blood derivatives of human origin.

3.1.4.4 Absorption/dispersion in the body

Blue Medical Devices B.V. states that Summit CTO PTCA balloon dilatation catheter does not contain substances that are absorbed or dispersed into the body during use.

3.1.4.5 CMR substances

Not applicable. Based on the biological safety evaluation (TF0.0812.0x) and the characteristics of the body contacting materials Blue Medical Devices B.V. states that Summit CTO PTCA balloon dilatation catheter does not contain substances that are carcinogenic, mutagenic or toxic to reproduction.

3.2 Previous generation(s) or variants

The Summit CTO PTCA balloon dilatation catheter is a Blue Medical Devices B.V. 4th Generation semi-compliant PTCA balloon dilatation catheter and is based on the Blue Medical Devices previous generations semi-compliant PTCA balloon dilatation catheters. The first Blue Medical Devices PTCA balloon catheter were successively improved in pushability and trackability, crossability dimensions of distal catheter section and deflated balloon, and lower guidewire friction and ultimately resulted in XW2 PTCA balloon catheter. The development of the currently marketed 4th generation Summit CTO PTCA balloon dilatation catheter was achieved by decreasing the balloon sizes (minimum 1.1mm diameter) and optimizing the XW2 PTCA catheter. The XW2 is not a currently marketed product.

3.3 Accessories intended to be used in combination with the device.

Blue Medical Devices B.V. states that Summit CTO PTCA balloon dilatation catheter is intended to be used in accordance with established minimally invasive / coronary catheterization procedures, which includes the accompanying devices that are required to be used in combination with the Summit CTO PTCA balloon dilatation catheter in these procedures.

3.4 Other devices or products intended to be used in combination with the device

Not applicable. Blue Medical Devices B.V. states that Summit CTO PTCA balloon dilatation catheter is not intended to be used in combination with specific accessories other than generic devices routinely required for the interventional PTCA procedure as described in the directions of use.

4 Risks and warnings

4.1 Residual risks and undesirable effects

The Risk Management process has assured that the hazards (failure modes) which could lead to potential harms to the patient were identified, and all reasonable practicable activities (risks mitigation measures) have been implemented to achieve risk acceptability through safety by design and/or in-line process controls, and usability risk control measures to prevent the hazards from occurring.

Improper use and/or handling by the user/customer cannot be eliminated through safety by design and/or in-line process controls. Usability risk control measures, to prevent hazards from occurring, have been implemented by appropriate labelling and/or IFU (procedure) text.

The implemented control measures are outlined in the below Table 2, which are covered in "warnings and precautions" as listed in section 4.2.

Table 2: Potential harms and implemented usability risk control measures

Potential harm	Implemented usability risk control measures in IFU and/or labelling	Occurrence rates (per unit sales)
		Official Complaints + PMCF data
Air-embolism	Instructions on preparation and that the use of the device is to be performed by qualified physicians.	0%
Embolism	Instruction and/or warning and/or labelling on single use device, hub product identification, fluoroscopic control, catheter handling.	0%
Major vessel dissection	Instructions and/or warnings on Rated Burst Pressure, compliance chart, fluoroscopic control, catheter handling.	0%
Vessel perforation and/or rupture	Instructions and/or warnings on Rated Burst Pressure, compliance chart, fluoroscopic control, hub product identification, catheter handling.	0%
Acute Myocardial Infarction	Instructions and/or warnings on Rated Burst Pressure, compliance chart, catheter handling.	0%
Infection	Easy opening box, and Instructions and/labelling indicating single use, "use before date", rough handling, following hospital procedure.	0%
Death	Instructions on procedure regarding in deflation, preparation device, catheter handling.	0%
Occlusion of coronary artery/bypass graft	Instruction warning and labelling on single use device.	0%
Additional percutaneous/surgical intervention	Instructions and/or labelling and/or warnings on device preparation, inflation & deflation procedure, hub product identification, Rated Burst Pressure, compliance chart, fluoroscopic control, catheter handling, "use before date".	0%

Percutaneous devices used for dilatation of target lesions are an integral part of coronary catheterization. There are potential complications that could be encountered during all coronary catheterization procedures which cannot be further reduced by taking design and/or inline process controls risk mitigation measures and/or through protective measures or information for safety.
Therefore, potential complications (harms) that can be encountered during all coronary catheterization procedures (either with or without the application of angioplasty devices under normal conditions of use) are listed in the IFUs of the Blue Medical Devices PTCA balloon dilatation catheters. These potential harms can include, but are not limited to:

- Death.
- Acute myocardial infarction.
- Total occlusion of the coronary artery or bypass graft.
- Coronary vessel dissection, perforation, rupture or injury.
- Restenosis of the dilated vessel.
- Haemorrhage or haematoma.
- Unstable angina.
- Arrhythmias, including ventricular fibrillation.
- Drug reactions, allergic reaction to contrast medium.
- Hypo/hypertension.
- Infection.
- Coronary artery spasm.

- Arteriovenous fistula.
- Embolism.
-

4.2 Warnings and precautions

Warnings and precautions related to the preparation of a device or relating to procedural steps are contained in the IFU.
The IFU can be assessed on the manufacturer's website: ***www.translumina.com***

Warnings

· For single patient, single procedure use only. Do NOT resterilize and/or reuse as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
· To reduce the potential vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
· PTCA in patients who are acceptable candidates for coronary artery bypass graft surgery requires careful consideration. This includes possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
· When the balloon dilatation catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic guidance. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
· Balloon Pressure: do not exceed the rated burst pressure (RBP) indicated on the packaging. The rated burst pressure (RBP) is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure (RBP).
· Use of a pressure-monitoring device is recommended to prevent over pressurization.
· PTCA should only be performed at hospitals where emergency coronary bypass surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
· Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
· Use the catheter prior to "Use Before" ("expiry") date specified on the package.
· Treatment of vessels with moderate or heavy lesion calcification is associated with decreased success rates up to 60-85% and increases the risk of acute closure vessel, trauma, balloon burst, balloon entrapment and associated complications.

Precautions

· Prior to angioplasty procedure, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it will be used.
· Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the catheter.
· During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN)

Not applicable. There have been no FSCA.

5 Summary of clinical evaluation

5.1 Summary of clinical data related to the equivalent device

Not applicable.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking

No clinical investigations were conducted with the Summit CTO PTCA balloon dilatation catheter prior to CE-certification (MDD 93/92/EEC) in 2009.

5.3 Overall summary of the clinical performance and safety

5.3.1 PMCF procedure data

Besides regular Post Market Surveillance (PMS), Post Market Clinical Feedback (PMCF) was collected on clinical procedure data from multiple physicians (end-users) in various countries in- and outside of Europe.

The clinical application of 37 Summit CTO PTCA balloon dilatation catheters was evaluated in between September 2008 to Dec 2023. Physicians rated catheter characteristics relevant to the performance and safety of the Summit CTO PTCA balloon dilatation catheter, and indicated if any safety issues had occurred. A summary of the PMCF data is given in *Table 3*.

Table 3: Summary of pivotal PMCF data

Year	Evaluators	Summary SUMMIT CTO PTCA balloon dilatation catheter data
2008	8 Physicians (end-users) in 5 hospitals in the Netherlands and Germany.	N=20 Summit catheters were evaluated during PCI procedures of CTO lesions (procedure data). Most performance characteristics were rated as good/acceptable for >88% of balloons. Lesion positioning was successful in 68%. Lesion crossability was good in 65% and poor in 10% of cases; failures were due to inability to cross the lesion (n=5), and the one poor crossability given as balloon burst in the lesion, all due to severe calcification. One of these failed crossability could not be recrossed with another competitor balloon; one was crossed with a larger, stiffer balloon, and in one case a smaller competitor balloon was used successfully. Profile was good (76%) and acceptable (12%). The RBP is 15 bar for the Summit; however, the mean inflation pressure was 18±3.6 bar (n=34 inflations), with all but 8 inflations ≥18 bar (max 26 bar), demonstrating the robustness of the balloon. Overall performance was given for n=15 catheters, which were rated as good (87%) and acceptable (13%).
2016	Physician (end-user) Vietnam	N=1 Summit PTCA catheter. In 2016 one evaluation form filled out by a physician from Vietnam was received. A type B1 lesion in the LAD was treated with the Summit PTCA catheter. There was no vessel tortuosity, no lesion calcification and no thrombus present. All performance characteristics were rated good. *(Preparation, Positioning, Flexibility, Profile, Pre-Dilatation, Crossability, Post-Dilatation, Trackability, Pushability, Deflation, Rewrap, Handling, Overall)*.
2019	Physicians (end-users) in 4 hospitals in the Netherlands	N=4 Summit PTCA catheters were used for predilatation during PCI procedures (procedure data) as part of the Investigator-initiated Pearl (DEB) study. Comparable competitor semi-compliant PTCA devices (Tazuna, n=5; Ryujin, n=2; MiniTrek, n=3) (with balloon diameter ≤1.5mm) were also used in the study for predilatation. The study included 513 patients (2014-2019). All Summit PTCA successfully crossed the de novo (n=2) and ISR (n=2) lesions (99% stenosis; type C, n=3; type B1, n=1) in LAD (n=2), RCA, and vein graft vessels. Calcification was *heavy* (n=1) requiring 3 inflations @ 16 atm; *moderate* (n=2) requiring 2 inflations @ 15 and 16 atm, and 1 inflation @ 14 atm.; and *mild* (n=1) requiring 1 inflation @ 14 atm. All pre-dilatations were successful, and followed either by SC DEB or NC DEB treatment. Summit PTCA shows comparable performance to

		competitors in comparable vessels and lesions. All Summit procedures / dilatations were without device failures or safety events.
2021	Physicians (end-users) (N=2) in Latvia and Taiwan	Feedback on n=3 Summit PTCA catheters. Lesions type C and B1 in LAD, with moderate and no calcification, respectively. Type C lesion was treated with a 1.1x15mm Summit, with 2 inflations at 4 bar. Type B2 lesions at 20 bar. All Summit balloons were inflated multiple times. Overall performance was good and acceptable. There were no device anomalies and no safety issues.
2023	Physicians (end-users) (N=4) in France and Pakistan	Feedback on n=9 Summit PTCA catheters. Data from nine cases involving the use of SUMMIT PTCA balloons in France and Pakistan. The cases in France span hospitals Schweitzer, HAS, and Blue Medical, while all cases in Pakistan were handled at NICVD, including NICVD Karachi. Lesion locations include the Mid RCA, 1st Ob Marg, Mid RCX, Distal RCA, and Proximal RCA. Lesion types are mainly Type C, with a few Type A, B1, and B2. Vessel tortuosity varies, with cases showing no, moderate, and severe tortuosity. Calcification is present in most cases. The balloons used have diameters of either 1.10 mm (n=6) or 1.20 mm(n=3), with lengths of 10 mm, 15 mm, and one case of 20 mm. Maximum inflation pressures range from 8 (n=3)to 10 bars(n=2), For other n=4 catheters the inflations pressure data was not available. Only 1 Summit balloons was inflated multiple times (2 times). None of the Summit catheters were used for more than one lesion. The overall performance of the Summit CTO PTCA balloon dilatation catheter was rated excellent (n=5), and Similar (n=1) in 2023. There were very limited no. of feedback forms collected for PTCA catheters. Therefore, PMCF data collection will be continued throughout 2024. The data does show only excellent ratings, indicating acceptable clinical performance of the Summit. The current rates show that the Summit CTO has acceptable clinical performance. No adverse events were recorded via PMCF and no new risks or side-effects were identified. Overall performance was good and acceptable. There were no device anomalies and no safety issues.

5.3.2 Blue Medical Devices B.V. Complaints database

Total n=4 customer complaints were received by Blue Medical Devices from 2013-2023 involving the Summit CTO PTCA balloon dilatation catheter and/or packaging. Sales data was available from 2013-2023. For this period, based on the total units sold the overall complaint occurrence rate is 0.013%. Of the total 4 complaints, two were pre-procedure (unpacking the device) and two intra-procedures (no lesion crossing). There were no patient injuries/harm reported.

The below Table 4 gives an overview of the Summit CTO PTCA balloon dilatation catheter procedure failures (Blue Medical complaints database + PMCF) and correspondence with those failures registered for competitor PTCA balloon catheters in the FDA Maude database.
During the life-time of the Summit CTO PTCA balloons dilatation catheters, the reported complaints and events show no new risks or hazards.

Table 4: Overview of device-related identified procedure failures (hazards) comparison literature and Summit CTO PTCA balloon dilatation catheter

Device-related identified procedure failures (Hazards)		
Literature	**Summit CTO PTCA balloon dilatation catheter: Complaints Database Manufacturer + PMCF**	
Failures for competitor PTCA balloon dilatation devices	**Reported Failure**	**Number (n) & Occurrence [n/total units sold]**

reported in FDA Maude database		
Balloon Rupture	Balloon burst	**Summit** PTCA: n=1. [0.003] (PMCF)
Material Split/cut or Torn		
Material Rupture (Shaft/balloon)		
Detachment of Device or device Component		
Deflation Problem		
Difficult to Remove		
Material Puncture / Hole		
Entrapment of Device		
Difficult to Advance	Trackability (guidewire problem)	**Summit** PTCA: n=1 [0.003]
Failure to Advance	Lesion crossability problems	**Summit** PTCA: n=7 [0.02] (n=5 in PMCF 2018; n=1 complaints 2013-2023)
Material Integrity Problem		
Material Deformation		
Failure to Fold		
Inflation Problem		
Device Damaged by Another Device		
Incorrect compliance chart		
Fracture Shaft		
Fracture Luer		
Improper or Incorrect procedure (not following IFU/labelling)		
Pre-procedure fracture (catheter damage)	Unpacking product difficulties/ pre-procedure catheter damage/break, tip damage, kink-bending	**Summit** PTCA: n=2 [0.006]

There were no Field Safety Corrective Actions (FSCA) during the life-time of the device as a result of complaints with clinical risks. All identified hazards and possible complications (risks) have been taken into account in the Risk Management Process of the Summit PTCA balloon catheter.

5.3.3 Summary conclusion

The clinical data generated for the marketed Summit CTO PTCA balloon dilatation catheter covers all safety aspects for the clinical application of the device, and gives confirmation on the clinical safety, performance and usability of the device for its intended purpose (use).

5.4 An overall summary of the clinical performance and safety

The clinical performance and safety data generated for the marketed Summit CTO PTCA balloon dilatation catheter covers all performance aspects for the clinical application of the device and gives confirmation on the performance of the device for its intended purpose (use). The performance and safety clinical data presented, as well regular PMS feedback, shows acceptability of all performance characteristics of the Summit CTO PTCA balloon dilatation catheter. The number of device failures

reported in the Blue Medical Devices B.V. complaints database over the lifetime of the Summit CTO PTCA balloon dilatation catheter is low.

The claimed clinical benefits are supported by the documented data:

- For patients suffering from stenotic lesions in the coronary artery system that require PCI, PTCA balloon catheter characteristics shows clinical benefits in that following successful guidewire crossing of the target lesion, catheter procedure technical success of 91.6% was achieved for the Summit CTO PTCA balloon dilatation catheter, with the benefit of optimizing lesion preparation for an overall successful PCI procedure for improving myocardial reperfusion. Technical success encompasses catheter characteristics of delivery, lesion crossing, inflation/deflation, rewrap, removal / retraction from the target lesion, through vessels and back into the guiding catheter.

The claimed clinical performance objectives are supported by the documented data:

- The clinical performance data, and design verification and validation data, generated for the Summit CTO PTCA balloon dilatation catheter provides sufficient clinical evidence to demonstrate clinical performance of the Summit CTO PTCA balloon dilatation catheter for the intended use. The Summit CTO overall performance technical success rate of 91.6% is slightly lower than the ≥95% performance objective. The 2016/2019 data showed 100% technical success, however, the technical failure of “lesion crossing failure” in the first PMCF in 2008 was the main component resulting in the combined data overall 91.6% technical success. There was no reported device-related adverse events. Since 2011-current only n=2 Summit CTO PTCA balloon dilatation catheter complaints [per total sales an occurrence of 0.006] were reported related to failed lesion crossing. Since the 2008 era (in the last decade), there have been improvements in techniques and support devices for CTOs to increase crossability success in these challenging lesions.

The claimed clinical safety objectives are supported by the documented data:

- The clinical data generated for the marketed Summit CTO PTCA balloon dilatation catheter covers all safety aspects for the clinical application of the device) and gives confirmation on the clinical safety of the device for its intended purpose (use). The safety criteria (completion of procedure without PTCA balloon catheter-related procedure serious adverse events (<1%)) was met. There were no (0%) device-related serious adverse events reported.

5.5 Overall conclusion of the Benefit/Risk Acceptability Assessment

Based on the data available in the current literature, the risks associated with the Blue Medical Devices PTCA catheters are anticipated to be no greater than those associated with other intravascular devices intended for the balloon dilatation in the coronary artery for the purpose of improving myocardial reperfusion during a PCI procedure.

The Blue Medical Devices SC PTCA dilatation catheter Summit CTO PTCA balloon dilatation catheters, feature design characteristics that will be beneficial in terms of deliverability (pushability, trackability), lesion crossability, balloon crossing profile, balloon compliance, inflation (vessel narrowing dilatation) / deflation.

Conclusion of the Benefit/Risk assessment: The overall residual risk is acceptable when weighed against the benefit.

5.6 Summary of evaluation of undesirable side effects

The hazards (failure modes) which could lead to potential harms to the patient were identified, as given in Table 2 in section 4.1, and all reasonable practicable activities (risks mitigation measures) were implemented to achieve risk acceptability by safety by design and/or in-line process controls and usability risk control measures to prevent the hazards from occurring. The accumulated clinical data for

the Summit PTCA balloon dilatation catheter indicates that there were no reported occurrences of the potential harms.
All percutaneous devices used in coronary catheterization procedures are for single use / single procedure only and must not be resterilized and/or reused as this could potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination. A warning is included in the labeling/IFU.
The individual and overall residual risks are determined not to be different compared to the state of the art.

5.7 Ongoing or planned post-market clinical follow-up

As part of the Post Market Surveillance program, Blue Medical Devices B.V. will continue performing annual Post Market Clinical Follow-Up (PMCF) in the form of a user-survey(s) on Summit CTO PTCA balloon dilatation catheters to obtain continuous extensive customer feedback on procedure safety and performance, and usability. The need for a PMCF study will be continually assessed according to the risk management process.
Based on the outcome of the risk management process, there are no residual risks or uncertainties or unanswered questions that would require specific evaluation during PMS.

6 Possible diagnostic or therapeutic alternatives

Stand-alone balloon angioplasty intervention (or plain old balloon angioplasty [POBA]) is no longer the common treatment approach. Therefore, in current practice balloon angioplasty is most often applied in procedures in which devices such as drug-eluting balloons and/or coronary drug eluting stents are the "main" procedure treatment component.
State of the Art literature indicates a number of alternative treatments and/or devices:

- Drug-eluting balloons (DEB): DEB catheters are conventional (standard) semi-compliant or non-compliant angioplasty balloons covered with an anti-restenotic drug, which is released into the vessel wall during inflation of the balloon, for better long term outcomes with respect to lesion restenosis. The complications that can occur with a DEB PTCA catheter are no different to those of standard balloon angioplasty catheter in terms of the peri-procedure complications. Standard semi-compliant and non-compliant PTCA balloon catheters are often used to pre-dilate the lesion prior to DEB application.
- Coronary drug-eluting stents (DES) are the most widely used intracoronary devices in PCI due to improved *longer term* clinical outcomes. Standard semi-compliant and non-compliant PTCA balloons are often used for pre- and/or post-dilatation.
- Coronary Artery Bypass Grafting (CABG) has been considered the standard of care for patients with unprotected left main (LM) CAD (i.e. patients without prior CABG or a patent graft to the left anterior descending (LAD) or left circumflex artery), a reasonable alternative to CABG is PCI to improve survival in selected stable patients who have ≥50% diameter stenosis and either of the following:
    - Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g. stenosis of the ostium or trunk vs distal bifurcation or trifurcation stenoses)
    - Clinical characteristics that predict a significantly higher risk of adverse surgical outcomes

  A consideration in the choice of CABG rather than PCI is if the patient does not tolerate or comply with dual antiplatelet therapy (DAPT).
- Rotational and Orbital Atherectomy. Atherectomy can be used for specific lesions unsuitable for balloon angioplasty and/or stent.
- A cutting and scoring PTCA catheters are balloon lesion-tipped catheters with respectively cutting (micro-blades) and scoring elements attached, which are used in those circumstances where a lesion is resistant to high pressure balloon dilatation.

- Medical therapy is recommended as first-line therapy in patients with stable angina unless one or more of the following indications for cardiac catheterization and PCI or CABG are present:
  - Severe symptoms
  - A change in symptom severity
  - Failed medical therapy
  - High-risk coronary anatomy or noninvasive findings
  - Worsening left ventricular dysfunction

Medical Society Guideline: F.-J. Neumann *et al.*, "2018 ESC/EACTS Guidelines on myocardial revascularization The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) Developed with the special contribution of the," *Eur. Heart J.*, vol. 40, no. 2, pp. 87–165, 2019, doi: 10.1093/eurheartj/ehy394.

7 Suggested profile and training for users

The target users are medical professionals who perform and assist in catheterization procedures in a clinical laboratory setting, during percutaneous intervention (e.g. PTCA, coronary stent placement).
Use of the product is restricted to healthcare professionals in an interventional suite with angiography equipment, with personnel with relevant and adequate training and who familiar with the possible/conceivable complications. The Blue Medical Devices PTCA catheter can only be purchased on prescription of a physician.

8 Reference to any harmonized standards and CS applied

Key applicable (harmonised) standards and guidance documents specifically for PTCA:

- ISO 10555-1:2023 Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
- ISO 10555-4:2023 Intravascular catheters – Sterile and single-use catheters – Part 4: Balloon Dilatation Catheters
- ISO 10993-1:2021 - Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- ISO 10993-4:2017-10 - Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-7:2008/A1:2022 - Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
- ISO 11135:2014/A1:2019 - Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices
- ISO 11607-1:2020/A1:2023 - Packaging for terminally sterilized medical devices. Part-1 Requirements for materials, sterile barrier systems and packages systems
- ISO 11607-2:2020/A1:2023 - Packaging for terminally sterilized medical devices. Part-2: Validation requirements for forming, sealing and assembly processes
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

9 Revision history

SSCP Revision number	Date issued	Change description	Revision validated by the notified body	
01	13-06-2022	First issue	X	Yes Validation language: English
			☐	No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	08-08-2024	Review and update for the fiscal year 2023.	☐	Yes Validation language: English
			X	No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)