Summary of Safety and Clinical Performance
Vision-MR Diagnostic Catheter

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1. Introduction

1.1 Purpose

This document provides the summary of safety and clinical performance for the Vision-MR Diagnostic Catheter in compliance with MDCG 2019-9.

1.2 Definitions

Term	Definition
Clinical Evaluation	A methodologically sound ongoing procedure to collect, appraise and analyze clinical data pertaining to a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant general safety and performance requirements when using the device according to the manufacturer's Instructions for Use. (MEDDEV 2.7/1 rev. 4)
CND Code	"Classificazione Nazionale dei Dispositivi medici" or "National Classification of Medical Devices" codes are the basis for the EUDAMED device database nomenclature. CND codes will be mapped to Global Medical Device Nomenclature (GMDN) for ease of use.
Basic UDI-DI	The Basic UDI-DI is the primary identifier of a device model. It is the device identifier (DI) assigned at the level of the device unit of use. It is the main key for records in the Unique Device Identifier (UDI) database and is referenced in relevant certificates and European Union (EU) declarations of conformity.
EUDAMED	European database on medical devices is a central repository for information on market surveillance. It will function as a registration system, a collaborative system, a notification system, a dissemination system (open to the public), and will be interoperable. (Europa)
Post-Market Clinical Follow-up (PMCF) Study	A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e., residual risks) of a device when used in accordance with its approved labelling. (MEDDEV 2.12/2 rev.2)
Periodic Safety Update Report (PSUR)	Summary of the results and conclusions of Post Market Surveillance (PMS) data along with a rationale and description of any corrective actions taken for products on the market. Manufacturers of class IIb and class III devices shall update the PSUR at least annually. Manufacturers of class IIa devices shall update the PSUR at least every two years.

2. Summary of Safety and Clinical Performance for Healthcare Professionals:

This SSCP is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the Vision-MR Diagnostic Catheter.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

2.1 Device Identification and General Information

Device Identification and General Information	
Device Trade Name(s) and Model Number(s)	Vision-MR Diagnostic Catheter (VMRD102)
Manufacturer	Imricor Medical Systems, Inc. 400 Gateway Blvd. Burnsville, MN 55337, USA
Manufacturer's SRN	US-MF-000017310
BASIC UDI-DI	00854277008VMRD1XXSG
Medical Device Nomenclature (CND Code)	C020101 Aritmology, Bipolar Electrocatheters
Device Class	Class III
Initial Certificate (CE) Issuance	CE-Marked
Authorized Representative	MedR-AR Services Kloosterweg 1 NL 6412 CN Heerlen +31 45 3030 006 SRN: NL-AR-000000120
Notified Body (NB)	TUV SUD Product Service GmbH Zertifizierstellen (0123) Ridlerstraße 65 80339 MÜNCHEN, Germany

2.2 Intended Use of the Device

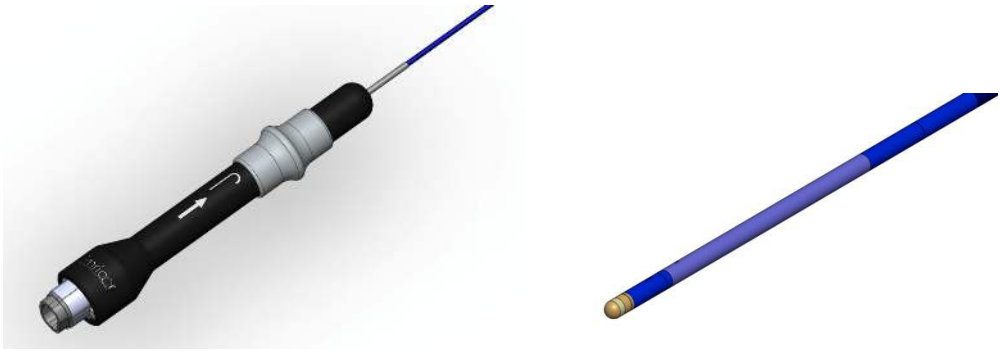
Intended Purpose of the Device	
Intended Purpose / Intended Use	The Vision-MR Diagnostic Catheter is intended for cardiac electrophysiological mapping (stimulating and recording) during electrophysiology procedures to diagnose arrhythmias and/or guide therapeutic decisions in patients 18 years and older.
Indications for Use	To diagnose arrhythmias and/or guide therapeutic decisions during electrophysiology procedures
Intended User	A physician who performs electrophysiology procedures
Patient Population	Patients undergoing electrophysiology procedure that are 18 years or older.
Intended part of the body/type of tissue applied to or interacted with	The catheter is introduced percutaneously into the vasculature and then maneuvered into the heart.
Contraindications/ Limitations	The Vision-MR Diagnostic Catheter is contraindicated for use in patients: -Who have had a ventriculotomy or atriotomy within the preceding eight weeks; -With a prosthetic valve through which the catheter must pass;

	-With an active systemic infection; -With a myxoma, or an intracardiac thrombus; -With an interatrial baffle or patch through which the catheter must pass.

2.3 Device Description

Device Description	
General Description	The Vision-MR Diagnostic Catheter is a MR Conditional single-use, sterile diagnostic catheter. The purpose of the diagnostic catheter is to facilitate sensing and pacing during cardiac electrophysiology procedures. The Vision-MR Diagnostic Catheter is designed for use with the Advantage-MR EP Recorder/Stimulator System (Advantage-MR).
Operating Principals	The device acts as a probe to facilitate sensing electrical activity of the heart and delivering pacing stimuli to the heart.
Accessories	Advantage-MR EP Recorder/Stimulator System (AD-001 and AD900) Vision-MR Diagnostic Catheter Cable (CABD102)
Sterility	Sterile device. Sterilized via 2x EtO
French Size	9F
Usable Length	115 cm
Usage	Single use
Electrodes	2
Device Materials	The Vision-MR Diagnostic Catheter is biocompatible as an external communication device in contact with circulating blood for a contact duration of less than 24 hours. Biocompatibility testing was conducted in accordance with ISO 10993 and determined no materials could result in sensitization or an allergic reaction to the patient or user. There are no medicinal, tissue or blood products incorporated in this product. There are no substances that are absorbed by or locally dispersed in the human body and there are no materials in the device that contain or consist of CMR substances or endocrine-disrupting substances. The table below identifies the raw materials incorporated into the key functional elements either in direct or indirect contact with the human body.

Component	**Raw Material**	**Direct/Indirect Body Contact**
Catheter Shaft	Pebax (72D, 55D, 40D, 35D) Blue Pantone 295C Blue Pantone 2945C	Direct
Ring Electrode, 9Fr	99.9% Gold	Direct
Tip Electrode, 9Fr	99.9% Gold	Direct
Electrode Tip Support	PEEK, natural	Direct
Catheter Shaft Strain Relief	Polyolefin	Direct
UV Adhesive, 4306	Cyanoacrylate	Direct
UV Adhesive, 4310	Cyanoacrylate	Direct

Device Drawings	

2.4 Key Functional Elements

2.4.1. Catheter Control Mechanism

During an interventional procedure, the catheter is physically maneuvered using the following mechanisms:

- Advancement and retraction of the catheter
- Rotation of the catheter
- Deflection of the catheter

The catheter shaft is constructed using industry standard medical grade materials and is reinforced with polymer braiding to provide advancement and torque response similar to existing braided catheters. As is the standard in the industry, advancement of a thumb control mechanism on the catheter handle retracts a pull wire within the catheter shaft and deflects the catheter tip. This deflection action allows the catheter to be directed within the cardiac anatomy.

2.4.2. Passive Catheter Imaging

The Vision-MR Diagnostic Catheter meets the requirements of ISO 10555-1 for conspicuousness in x-ray images. This is accomplished by doping the catheter shaft material with barium sulfate ($BaSO_4$). The catheter electrodes and electrode wire assembly are also visible under x-ray.

The catheter can also be visualized using standard MR imaging techniques by selecting an imaging plane that intersect with or is parallel to a subsection of the catheter shaft. Visualizing the catheter by either voids or local areas of enhancement it creates in MR images is referred to as “passive” tracking or visualization. Passive catheter tracking does not utilize active electronics or communication with the MRI to determine the catheter position. It relies solely on identifying the catheter in MR images of the cardiovascular anatomy.

2.4.3. Active Catheter Imaging

“Active imaging” refers to the process of using MRI signals received by miniature receive coils on a medical device to visualize the position of the device in real-time. During active imaging, the coil appears as bright spot in the MR image. The imaging plane can be either manually or automatically interactively manipulated during imaging to keep the coil in the imaging plane.

To facilitate active imaging, the Vision-MR Diagnostic Catheter has one miniature MRI receive coil integrated into the distal tip of the catheter. When used for active imaging, the receive coil in the catheter is connected to a receive channel of the MRI via Advantage-MR and the MRI interface. This allows the MRI to receive signals from the coil in the catheter.

2.4.4. Active Catheter Tracking

"Active tracking" refers to the process of using MRI signals received by miniature receive coils on a medical device to track the position of the device in real-time. It is an automated and continuous process of determining the device position and visualizing the device in MR images or segmented shells representing relevant anatomic structures.

To facilitate active tracking, the Vision-MR Diagnostic Catheter has one miniature MRI receive coil integrated into the distal tip of the catheter. When used for active tracking, the receive coil in the catheter is connected to a receive channel of the MRI via Advantage-MR and the MRI interface. This allows the MRI to receive signals from the coil in the catheter.

When actively tracking the catheter, the MRI processes signals received by the miniature receive coil in the catheter to determine the three-dimensional coordinates of the receive coil within the MRI imaging volume. This allows the location of the coil to be identified within the MR system's field of view.

Commercially available conventional catheters use sensors which are external to the patient for catheter tracking. Some use additional sensors within the catheter. These tracking techniques must all be calibrated and registered to the imaging used during the procedure.

The Vision-MR Diagnostic Catheter uses the MR imaging modality, itself, for tracking. Since the same mechanism generates anatomical images and determines the catheter position, the resulting catheter position is by definition calibrated and registered to the images.

2.4.5. Intracardiac Sensing and Pacing

The Vision-MR Diagnostic Catheter facilitates sensing of intracardiac electrograms and cardiac pacing during electrophysiological procedures. A brief description of each of these functions is provided below.

2.4.6. Sensing Intracardiac Electrograms

The Vision-MR Diagnostic Catheter is used with Advantage-MR to sense and record intracardiac electrograms. To sense intracardiac electrograms, the catheter acts as a probe and conducts the voltage difference between the catheter electrodes to sensing circuitry in Advantage-MR. Advantage-MR then filters and displays the electrograms.

2.5 Risks and Warnings

The risk management activities for the Vision-MR Diagnostic Catheter identified risks applicable to the design and use of the device and determined the overall residual risk. Analysis of the residual risks took into consideration the clinical data from the equivalent device, the current state of the art, preclinical data from the Vision-MR Diagnostic Catheter and equivalent device and scientific literature to determine the acceptability of each residual risk. The device labeling is suitable to address the intended use and residual risks of the device. The residual risks are address in the IFU through the warnings, precautions, contraindications, directions for use and list of potential adverse events.

2.5.1. Potential Adverse Events

The following table categorizes the potential adverse events for the Vision-MR Diagnostic Catheter used for electrophysiological procedures into one of the following categories: cardiovascular, pulmonary, neurological, anesthesia, or general procedure. The table includes the expected threshold level for each adverse event withing a given category. The potential adverse events listed were identified via review of the State of the Art, literature, clinical studies for the equivalent device, review of applicable databases and comparable competitive device instructions for use.

Adverse Event Category (Threshold Levels)	Adverse Events
Cardiovascular (Occasional < 1%)	• Arrhythmias (new or exacerbation of existing arrhythmias) • AV Block • Cardiac perforation/tamponade • Endocarditis • Lead dislodgement or components damage of implantable cardioverter/defibrillator/pacemaker • Myocardial infarction • Pericarditis • Valvular damage
Pulmonary (Extremely Unlikely < 0.01%)	• Hemothorax • Pneumothorax • Pulmonary embolism
Neurological (Extremely Unlikely < 0.01%)	• Cerebrovascular accident (CVA)/stroke • Transient ischemic attack (TIA)
Anesthesia (Extremely Unlikely < 0.01%)	• Allergic reaction • Anesthesia/sedative agent reaction
General Procedure (Reasonably Probable <10%)	• Air embolism • Arteriovenous fistula • Chest pain/discomfort • Death • Hematoma • Hospitalization (initial/prolonged) • Infections • Major bleeding/hemorrhage • Nerve injury (phrenic/vagus/diaphragmatic paralysis) • Pseudoaneurysm • Thrombosis • Thromboembolism • Tissue damage (burn) • Vasovagal reactions • Vessel trauma (perforation/dissection/rupture/obstruction)

The occurrence rates of the residual risks will be reviewed on a continuous basis to determine if a harm is occurring more than expected. If a harm is occurring more than expected the risk analyses will be updated and the overall benefit-risk analysis will be reassessed.

2.5.2. Warnings

1. Do not attempt to operate the Vision-MR Diagnostic Catheter prior to completely reading and understanding the Instructions for Use.
2. The Vision-MR Diagnostic Catheter is a single use device. Do not reuse or resterilize the catheter. Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness or death. Reuse or resterilization may also create a risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.
3. Only physicians trained in cardiac electrophysiology procedures should use this device. Appropriate clinical instructions in use of the Vision-MR Diagnostic Catheter should also be completed.
4. When used in an MR environment, refer to the MR Conditions for Use section of the IFU.
5. The interaction with implantable devices has not been evaluated by Imricor. Refer to the IFU and MR conditions of use for any implantable devices present.
6. To avoid thromboemboli, anticoagulation should follow standard therapeutic guidelines.
7. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation or tamponade during catheter advancement. Use appropriate imaging and electrogram data during catheter introduction and advancement to reduce the risk of tissue injury. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
8. Always pull the thumb control back to straighten the catheter tip before insertion or withdrawal of the catheter.
9. Discontinue use of the catheter if the catheter is not functioning properly.
10. Testing has not been conducted on pregnant women. This should be taken into consideration prior to using this device.

2.5.3. Precautions

1. Do not use the product after its use-by date.
2. Inspect all components before use. Do not use if the package or items in the package appear damaged or defective. Contact Imricor Medical Systems, Inc. with the model number, lot number, and unique device identifier (UDI) from the package label if the seal or package is damaged or if there are any concerns regarding product integrity.
3. Do not expose the catheter to organic solvents such as alcohol.
4. Do not autoclave the catheter.
5. Do not immerse proximal handle or cable connector in fluids; electrical performance could be affected.
6. Do not scrub or twist the distal tip electrode with respect to the catheter shaft during cleaning as twisting may damage the bond and loosen the tip electrode.
7. Insert catheter carefully into introducer to avoid damage to distal tip.

2.5.4. Safety (Other)

There are no field safety corrective action (FSCA) or field safety notices (FSN) for the Vision-MR Diagnostic Catheter.

2.6 Summary of Clinical Evaluation and Post Market Clinical Follow-Up (PMCF)

The Vision-MR Diagnostic Catheter was assessed and endorsed by the notified body on the basis of equivalence. The Vision-MR Diagnostic Catheter is considered clinically, technologically, and biologically equivalent to the Vision-MR Ablation Catheter (Basic UDI-DI 0854277008VMR1XXEV). The equivalent device is manufactured by Imricor Medical Systems. The Vision-MR Ablation Catheter SSCP is not currently available in EUDAMED. This section includes a summary of the pertinent clinical data for the Vision-MR Diagnostic Catheter and the equivalent device.

2.6.1. Summary of Clinical Investigation (Equivalent Device)

A premarket clinical investigation (IMR-2016) was performed for the equivalent device, the Vision-MR Ablation Catheter (VMR100-01). The Vision-MR Ablation Catheter is intended for cardiac electrophysiological mapping (stimulating and recording) and radiofrequency ablation for the treatment of type I atrial flutter in patients 18 years or older.

The study was a non-randomized, single arm cohort study. A total of thirty-six (36) subjects with type I atrial flutter were enrolled in the study, with thirty-five subjects being ablated with the Vision-MR Ablation Catheter. Subjects had follow-up visits 7-days, 3-months and 6-months post procedure. One subject was enrolled but was withdrawn from the study prior to catheter insertion. The study included the following study objectives and endpoints:

Objective: The objective of the study was to evaluate the safety and performance of the Vision-MR Ablation Catheter for the treatment of type I atrial flutter.

Primary Acute Performance Endpoint: Acute success defined as the demonstration of bidirectional cavo-tricuspid isthmus block after radiofrequency application in the cavo-tricuspid isthmus.

Primary Chronic Performance Endpoint: Chronic success defined as freedom from recurrence of type I atrial flutter at 3-months post procedure.

Secondary Performance Endpoint: Chronic success defined as freedom from recurrence of type I atrial flutter at 6-moths post procedure.

Primary Safety Endpoint: The rate of serious adverse events (SAEs) related to the device or procedure assessed at the 7-day follow-up.

Inclusion Criteria:

- First time indication for ablation of type I atrial flutter
- Age 18 or above
- Patients willing and able (mentally and physically capable per physicians' discretion) to understand the investigational nature, potential risks and benefits of the study and able to provide written informed consent to participate in the study and agree to comply with the follow-up visits and evaluation
- Patients able to receive anticoagulation therapy to achieve adequate anticoagulation

Exclusion Criteria:

- Contraindicated for MRI diagnostic exam
- A cardiac ablation or cardiac surgery within 180 days prior to enrollment
- Documented intracardiac thrombus, tumor, bleeding, clotting or other abnormality that precludes catheter introduction and placement
- Myocardial infarction within 60 days prior to enrollment
- Current unstable angina
- History of cerebrovascular event (within 180 days prior to enrollment)
- Patients with an ejection fraction less than or equal to 35% within 90 days prior to enrollment
- Permanent leads in or through the right atrium

- Clinically significant structural heart disease (including tricuspid valve regurgitation, tricuspid valve stenosis or other congenital heart disease) that would preclude catheter introduction and placement, as determine by the Investigator
- Uncompensated congestive heart failure (NYHA Class III or IV)
- Arrhythmia is secondary to electrolyte imbalance, thyroid disease, or other reversible or non-cardiovascular cause
- Known or sensitivity to heparin or warfarin
- Active or systemic infection
- Any other significant uncontrolled or unstable medical condition (including but not limited to hypertension and diabetes)
- Contraindicated for conventional ablation procedure due to known allergy against radiocontrast agents or renal insufficiency with glomerular filtration rate < 30ml/min/1,73m^2
- Women who are pregnant or plan to become pregnant within the course of their participation in the investigation or who are breastfeeding
- Life expectancy of less than 12 months
- Patients with prosthetic valves
- Contraindicated for transfemoral venous access
- Older than 75 years
- Current enrollment in any other clinical investigation

Results:

Subject Demographics:

The table below summarizes the demographic information of all subjects who enrolled in the study (n=36).

Characteristics	Values
Male (%)	35 (97.2)
Age (years)*	68.0 ± 6.6
Height (cm)*	177.5 ± 8.5
Weight (kg)*	90.9 ± 16.0

*Mean ± SD

Primary Acute Performance Endpoint:

	# Success / # Subjects Ablated	%	2-sided Exact Binomial 95% Confidence Limits
Bidirectional block of the cavo-tricuspid isthmus with the investigational catheter	32/35	91.4%	(0.77, 0.98)

Primary Chronic Performance Endpoint:

	# Success / # Subjects Ablated	%	2-sided Exact Binomial 95% Confidence Limits
Subjects in whom bidirectional block was achieved acutely and for whom 3-month data was available	32/32	100%	(0.89, 1.00)

Secondary Performance Endpoint:

	# Success / # Subjects Ablated	%	2-sided Exact Binomial 95% Confidence Limits
Subjects in whom bidirectional block was achieved acutely and for whom 6-month data was available	30/31	96.8%	(0.83, 1.00)

Primary Safety Endpoint:

	Number of Subjects Experiencing SAEs	%	2-sided Exact Binomial 95% Confidence Limits
Procedure or device related serious adverse events	4/35	11.4%	(0.03, 0.27)

The serious adverse events observed during the 7-day follow-up are summarized in the table below. These events were result of hospitalization and/or medical intervention.

Event	% (n=35)
Groin Hematoma	1 (2.9)
Pseudoaneurysm	2 (5.7)
AV Fistula	1 (2.9)
Device Replacement	1 (2.9)

The first four SAEs were related to the procedure: specifically, the vascular access site. All four of these events were resolved without further complication. The fifth SAE was a device replacement as a result of replacing the introducer sheath which caused the study device to become unsterile during the procedure. Results of the study were published in Paetsch et al.

No clinical investigations were conducted for the Vision-MR Diagnostic Catheter before CE-marking.

2.6.2. Summary of Literature Review

A literature review was performed for the Vision-MR Diagnostic Catheter and Vision-MR Diagnostic Catheter Cable. The purpose of the literature review was to evaluate published clinical literature relevant to the state of the art, safety, efficacy and clinical benefits of the Vision-MR Diagnostic Catheter and Vision-MR Diagnostic Cable. The scope of the review was limited to diagnostic catheters used for electrophysiology mapping.

Clinical literature, TPLC data, MAUDE data, and competitive device IFUs reported on types of adverse events and technical complications related to diagnostic catheters. The data summarized in the report provides benchmarks for measuring and comparing the safety and performance of the Imricor Vision-MR Diagnostic Catheter and demonstrates the effectiveness of the predicate devices when used to facilitate sensing and pacing. Sections 2.6.2.1 and 2.6.2.2 summarize the technical complications and clinical benefits reported in the clinical literature. Information regarding State of the Art and possible diagnostic and therapeutic alternatives can be found in Section 2.7. References to the articles selected as part of this literature review are located in **Section 4** of this SSCP.

2.6.2.1. Technical Complications

Of the fourteen selected articles that reported on adverse events, seven reported no complications related to the diagnostic catheter or procedure. The remaining articles reported instances of pericardial effusion, coronary injury, cardiac effusion/tamponade, AV block and hematoma. The complications reported were not attributed to the diagnostic catheter.

2.6.2.2. Clinical Benefits

Multiple articles selected for review evaluated the clinical benefits of various image guidance platforms used for arrhythmia ablation using diagnostic catheters. These articles discussed the benefits of moving away from fluoroscopy guided ablation procedures with some focusing on the benefits of using 3D electroanatomical mapping systems and intracardiac echocardiography devices while others focused on the clinical benefits of cardiac magnetic resonance guided procedures[2,3,5].

In addition to the discussion of image guidance, Biewener discussed the clinical benefits of multipolar mapping catheter including shortened mapping time. The article stated that the creation of voltage maps for arrhythmia procedures can be time consuming and the use of a multipolar mapping catheter reduced the mapping time by more than 60% when compared to the time needed to create similar maps with an ablation catheter.

2.6.3. Summary of Preclinical Animal Data

Two system level preclinical studies were performed to evaluate the feasibility of treating type I atrial flutter with the Vision-MR Ablation Catheter in a clinical iCMR laboratory. In total, ten swine underwent a cardiac mapping ablation procedure designed to mimic all aspects of the workflow for treating type I atrial flutter in an MR EP interventional laboratory. An additional preclinical study was performed to validate the use of the Vision-MR Diagnostic Catheter during diagnostic electrophysiology procedures.

2.6.4. Post Market Clinical Data

The Vision-MR Diagnostic Catheter is planned for market release in 2025, therefore there is no post market clinical data at this time. Data from the Post Market Clinical Follow-Up study described in Section 2.6.4 will be added to this section upon study completion.

Post-market surveillance activities for the Vision-MR Diagnostic Catheter will begin upon marketapproval for the device. This data will be used to identify new or changed likelihoods of residual risks, significant increase in the frequency or severity of incidents, and any identified adverse trends.

2.6.5. Summary of Clinical Performance and Safety

The data presented in the clinical evaluation report supports the conclusion that the Vision-MR Diagnostic Catheter is safe and performs as intended. Evaluation of the clinical and preclinical data from the equivalent device, the preclinical testing of the Vision-MR Diagnostic Catheter as well as clinical data from the literature, adequately establishes the clinical safety, performance, and MR Conditional use of the Vision-MR Diagnostic Catheter.

The risks associated with the use of the device are acceptable when weighed against the benefits to the patient and the current knowledge/state of the art. The data relevant to the Vision-MR Diagnostic Catheter is sufficient to demonstrate safety and performance of the device per the intended use as well as compliance with the General Safety and Performance Requirements.

The device labeling is suitable to address the intended use and residual risks of the device. The residual risks are address in the IFU through the warnings, precautions, contraindications, directions for use and list of potential adverse events. The residual risks identified for the Vision-MR Diagnostic Catheter are consistent with diagnostic catheters currently on the market and are acceptable for CE Marking. The residual risks will be actively updated based on the results of post market clinical follow-up and post market surveillance activities.

The clinical data reviewed in the clinical evaluation is sufficient to demonstrate the safety and performance of the device for the intended use of catheter-based cardiac electrophysiological mapping (stimulating and recording).

2.6.5.1. Safety Analysis

Potential adverse events listed in Section 2.5.1 were identified via a literature view and assessment of comparable competitive device instructions for use. The list of potential adverse events was corroborated by reviewing the procedural and device related adverse events from the clinical investigation (IMR-2016) for the equivalent device described in Section 2.6.

In addition, preclinical bench testing (electrical safety, MR safety, and mechanical testing) and animal studies (assessment of functionality and biocompatibility), directly collected information related to the safety of the device in relation to its intended use and did not uncover any unexpected adverse events.

This safety conformity assessment is based on the evidence provided by clinical investigation IMR-2016 and supported by the assessment of relevant clinical literature. While the literature review does not include information on the device under evaluation as it is planned for market release in 2025, it does provide information on the equivalent device and peer reviewed safety information for devices used for the same intended use and patient group that is representative of the intended treatment population.

The Vision-MR Diagnostic Catheter is designed to align with the current knowledge and state of the art diagnostic catheter functionality. As a result, the use errors expected with the Vision-MR Diagnostic Catheter and mechanical, biological, electromagnetic, and functional hazards are like those expected with conventional diagnostic catheters. The MR safety design risks related to the use of this device in the MR environment are unique to this catheter.

When cardiac electrophysiology procedures are performed in the conventional fluoroscopy lab, there is a risk of exposure to ionizing radiation for both the patient and operator. When used in the MR environment, the risk of exposure to ionizing radiation is eliminated, but new risks related to operating in the MR environment appear. These risks are controlled by the design of the Vision-MR Diagnostic Catheter and verified via bench testing in accordance with MR ASTM standards listed in Section 2.9. The Vision-MR Diagnostic Catheter has no restrictions as to where it can be used within the MR scanner room as long as it is used with the Advantage-MR EP Recorder/Stimulator System and with a 1.5T MR Scanner.

Post market clinical study data and post market surveillance information will be collected to corroborate the safety analysis performed. Details of the planned post market activities are in Section 2.6.6.

2.6.5.2. Performance Analysis

The Vision-MR Diagnostic Catheter is intended for cardiac electrophysiological mapping (stimulating and recording) during electrophysiology procedures to diagnose arrhythmias and/or guide therapeutic decision. This intended use is a subset of the intended use of the equivalent device, the Vision-MR Ablation Catheter, which is additionally intended for the therapy of radiofrequency ablation for the treatment of type I atrial flutter.

The clinical investigation (IMR-2016) for the equivalent device (Section 2.6) employed two Vision-MR Ablation Catheters for each case. One with the purpose of delivering the radiofrequency ablation therapy (ablation catheter) and the other for mapping purposes (reference catheter). Therefore, we can analyze the acute performance endpoint of demonstration of bidirectional conduction block as an indirect performance endpoint for the Vision-MR Diagnostic Catheter and the intended purpose of mapping (stimulating and recording). The chronic performance endpoints of freedom from recurrence at 3 months and 6 months post procedure are applicable to the Vision-MR Ablation Catheter's ability to perform radiofrequency ablation and are not analyzed further in this section.

The primary acute performance endpoint of demonstration of bidirectional conduction block in the cavotricuspid isthmus (CTI) requires the use of the reference catheter with the capabilities of stimulating and recording to confirm. The reference catheter was used to compare the signal propagation of a pace stimuli sent from the reference catheter in the coronary sinus to either side of the CTI in order to confirm bi-directional block. These measurements were taken prior to ablation and after ablation to show a delay in signal propagation across the CTI. The state of the art defines bidirectional conduction block as more than 50% prolongation of the conduction interval across the CRI or an absolute interval time of 150ms or greater after the ablation procedure with an acceptance rate of 90% for acute success[16].

With the capabilities of the reference catheter to map (sense and record) the acute performance endpoint of demonstration of bi-directional conduction block was confirmed in 32/35 patients for an acute success rate of 91.4% and absolute activation time of 177 ± 24ms across the CTI following ablation. In the three procedures where acute success was not achieved, the clinical ablation procedure was terminated prior to achieving conduction block, and the subject was transferred to a conventional fluoroscopy lab. Two of the three procedures were terminated after the subject developed an arrhythmia other than type I atrial flutter during the clinical ablation procedure, falling outside the intended use of the Vision-MR Ablation Catheter. The third procedure was terminated after several ablations were attempted with the Vision-MR Ablation Catheter and no observable tip electrode temperature rise was observed. All three failures for the CE Mark trial are related to the ablation capabilities or atrial flutter indication of the Vision-MR Ablation Catheter and would not have been considered failures for the Vision-MR Diagnostic Catheter as it is not intended for radiofrequency ablation.

Limiting procedural time and exposure to ionizing radiation and fluoroscopy in the traditional electrophysiology lab is an additional marker of success for electrophysiology procedures and indirect measurements of performance of the diagnostic catheter. For the CE Mark Study discussed above, the total procedure time was

similar to that of matched control atrial flutter procedures performed in the traditional catheterization lab under x-ray and fluoroscopy guidance.

The Vision-MR diagnostic catheter is MR-conditional and part of a suite of devices that allow EP procedures to be performed outside of the x-ray environment away from fluoroscopy and ionizing radiation exposure. In the CE Mark Study patients were only exposed to x-ray or fluoroscopy if the procedure could not be completed in the MR environment. This occurred in three of the thirty-five procedure (8.5%) with a total fluoroscopy time per procedure as 0.12 ± 0.46 minutes and (0-3 minutes). This rate of fluoroscopy exposure meets the acceptance criteria of 17 ± 10 minutes with a range of (2-46 minutes) occurring in 10% of patients defined in the state of the art.

Additionally, the performance of the Vision-MR Diagnostic Catheter was evaluated in a preclinical study. The study of the Vision-MR Diagnostic Catheter analyzed the intended use of catheter based cardiac electrophysiological mapping (stimulating and recording) with the design modifications between the Vision-MR Diagnostic Catheter and the equivalent device. These design changes include a shortened tip length, reduced number of receive coils, removal of the handle card and improved connector design. The study demonstrated the design modifications did not inhibit the Vision-MR Diagnostic Catheter from achieving the predefined endpoints and the device was able to sense and pace the heart, be visualized under MR imaging without generating image artifact, and be maneuvered to required anatomical locations to support its intended use.

In total, the performance analysis performed is based on data from a clinical investigation, animal testing and review of clinical literature. While the results of a clinical investigation are considered the highest level of clinical data evidence available, the equivalent device was the device under evaluation during the study. Therefore, prospective, post market clinical investigation data and post market surveillance data for the Vision-MR Diagnostic Catheter will be needed to corroborate the performance analysis performed. Planned collection and analysis of post market clinical data is detailed in the Diagnostic Catheter PMCF Plan (D00146).

2.6.5.3. Benefit-Risk Assessment

A clinical literature review established diagnostic catheters as the current state of the art for both diagnosis of arrhythmias and confirmation of arrhythmia termination post intervention. Diagnostic catheters similar to the Vision-MR Diagnostic Catheter have been in commercial use for over two decades and are well established in the field yet limited to use under fluoroscopy and x-ray. The benefits of using diagnostic catheters for cardiac electrophysiological procedures outweighs the risks, including the risk of exposure to ionizing radiation incurred through the use of x-ray imaging and guidance of the catheter.

The features of the diagnostic catheter vary, but all employ multi-electrode designs and robust deflection capabilities allowing the catheter to reach the various cardiac anatomies during electrophysiology procedures. Current diagnostic catheters are paired with image guidance platforms to improve imaging and navigation in the fluoroscopy and x-ray lab. These platforms leverage inputs from the mapping/diagnostic catheter to create 3D shells to enhance cardiac anatomy visualization and improve navigation compared to x-ray and fluoroscopy alone.

In addition, the Vision-MR Diagnostic Catheter is designed to be MR Conditional, which permits it to be used safely in the MR environment. Being safe for use in the MR environment offers the immediate benefit of a radiation free environment for patients and physicians. MR imaging during the procedure also allows for real-time soft tissue imaging of cardiac anatomy and substrate. Soft tissue imaging has the potential to improve first-time success rates of ablation procedures by providing ablation lesion visualization and verification. In addition, real-time assessment of cardiac substrate has the potential to allow physicians to deliver individualized ablation therapy strategies.

The data presented in the clinical evaluation report for the Vision-MR Diagnostic Catheter includes prospective clinical data for the equivalent device that demonstrates the Vision-MR Diagnostic Catheter is safe for cardiac electrophysiological mapping under MR guidance. The MR Safety, electromagnetic safety and biological characteristics for the equivalent device were consistent throughout the development of the device and are significantly similar to the device under evaluation. In addition, the same sterilization method, ethylene oxide, was used for both devices. Therefore, all exposures of the device to patients can be assessed for complications

related to the MR, electromagnetic, and biological safety of the device as well as the overall procedural use in the MR environment.

Based on the evaluation of clinical data relevant to the Vision-MR Diagnostic Catheter, there is no need for additional pre-market clinical data to support the safe use of the device. Post market clinical data will be gathered for the Vision-MR Diagnostic Catheter to corroborate the safety and performance of the device. Information on the post market clinical activities can be found in Section 2.6.4.

The labeling identifies the intended use, warnings, precautions, direction for use and MR conditions of the device. The IFU includes a list of potential adverse events associated with cardiac catheterization, which is consistent with diagnostic catheters currently on the market.

Taking into consideration the clinical data from the equivalent device, the current state of the art, the preclinical data, scientific literature analysis, and the assessment of potential adverse event data, the benefits outweigh the overall residual risks of using the Vision-MR Diagnostic Catheter and the device is determined to have a high level of safety consistent with stakeholder expectations. The overall residual risk of the Vision-MR Diagnostic Catheter is acceptable.

2.6.6. Post Market Clinical Follow-Up

The table below summarizes the activities that will be conducted as part of the post market clinical follow-up (PMCF).

Activity #	Planned Activity	Aim of Activity
1	PMCF study	• Confirming the safety and performance of the device • Identifying previously unknown side effects or monitoring the identified side effects and contraindications • Identifying and analyzing emergent risks on the basis of factual evidence • Ensuring the continued acceptability of the benefit risk ratio
2	Screen scientific literature	• Ensuring the continued acceptability of the benefit-risk ration of the device • Identifying and analyzing emergent risks on the basis of factual evidence
3	Actively monitor suitable registers	• Identifying possible systematic misuse or off-label use of the device, with a view to verify that the intended purpose is correct • Identifying and analyzing emergent risks on the basis of factual evidence

2.6.6.1. Post Market Clinical Follow-Up Study

A PMCF study is planned to support the lifetime of the device. The PMCF study will include a safety population of prospectively enrolled subjects to corroborate the safety of the Vision-MR Diagnostic Catheter. The study will include a safety population of 30 subjects.

Objectives	Description
Safety Objective	Provide corroborative evidence that the Vision-MR Diagnostic Catheter is safe as measured by the incidence of cardiovascular-specific adverse events (CSAEs) related to the Diagnostic Catheter at the 7-day follow-up. CSAEs are defined as one of the following events: cardiac perforation, pericardial effusion, pulmonary embolism, complete heart block, stroke, acute myocardial infarction, and death.

Endpoint	Description
Safety Endpoint	The rate of cardiovascular-specific adverse events (CSAE) assessed through the 7-day follow-up. The analysis will be based on a binomial proportion and expressed as a percentage. For a total of N subjects with S experiencing an CSAE, the percentage, represented as P, was calculated as P = 100 * S/N.

2.7 Possible Diagnostic or Therapeutic Alternatives

Diagnostic catheters are used to support diagnosis of arrhythmias, guide therapeutic decisions, and confirm successful treatment after an ablation procedure during cardiac electrophysiology (EP) procedures. Through sensing and recording of electrical signals in the heart and providing pacing stimuli, the diagnostic catheter is manipulated to different points within the cardiac anatomy to provide information about the timing and voltage of electrical signals propagated through the heart. This timing and voltage information is used by a trained clinician to then identify the source of an arrhythmia and/or to determine if successful arrhythmia termination has been achieved after treatment.

There are numerous styles of diagnostic catheters on the market today, including circular mapping catheters, HD grid catheters and traditional diagnostic catheters. The features of these catheters vary, but all employ multi-electrode designs and robust deflection capabilities allowing the catheters to reach the various cardiac anatomies required during EP procedures. The preferred diagnostic catheter design fluctuates based on physician preference and anatomical procedural needs[1,2].

A common term for the measurement of the electrical signals within the heart is electroanatomical mapping. Electroanatomical mapping (recording and stimulating) is the key purpose of diagnostic catheters on the market today, but the type of mapping utilized differs based on the catheter designs, the specific EP procedure being performed, and the arrhythmia being studied. For example, in two different studies evaluating atrial fibrillation, physicians employed two different diagnostic catheter designs and two different techniques to identify target tissue for treatment and confirm successful ablation of the arrhythmia. The SHINE study utilized a multi-electrode circular diagnostic catheter to develop a voltage map of the left atrium before, during and after left superior pulmonary vein isolation and utilized those maps to confirm entrance block in all treated PVs[1]. Porterfield, et al[2] compared three different diagnostic catheters and PVI confirmation techniques when evaluating pulmonary vein isolation in patients with atrial fibrillation. His study utilized a multi-pole circular mapping catheters along with an HD grid catheter for 3D mapping with varying PVI confirmation techniques including exit block confirmation, voltage mapping, loss of pace capture along ablation line, entrance block confirmation and activation mapping. Many studies employing a combination of multiple mapping techniques[2].

Finally, in Paetsch et al, the Vision-MR ablation catheter was used as a traditional diagnostic catheter for diagnosis and confirmation of treatment success (bi-directional block) during an atrial flutter procedure. The diagnostic catheter was used to compare the signal propagation timing of a pace stimuli sent from a reference catheter in the coronary sinus to either side of the cavotricuspid isthmus (CTI) to confirm bi-directional conduction block[7]. These measurements were done prior to and after ablation of the CTI to show a delay in signal propagation (bi-directional block) was achieved across the CTI.

Current commercially available diagnostic catheters are often paired with image guidance platforms to improve imaging and navigation in the fluoroscopy and x-ray lab. These platforms leverage inputs from the mapping/diagnostic catheters to create 3D shells to enhance cardiac anatomy visualization and improve navigation compared to x-ray and fluoroscopy alone[3]. These platforms have become a key focus in clinical research today as physicians and institutions strive to move away from their reliance on x-ray and fluoroscopy guided procedures due to the inherent hazards. The use of x-ray during interventional cardiovascular procedures exposes patients and medical staff to potentially dangerous, cumulative doses of ionizing radiation. Current research investigates the implementation of zero-fluoroscopy approaches including 3D-electroanatomical mapping and cardiac magnetic resonance (CMR) image guided interventions[4,5].

The Vision-MR Diagnostic Catheter leverages real time MRI for optimal visualization of the cardiac anatomy without requiring the additional time it takes to develop 3D shells with mapping software and tracking of

simplified diagnostic catheters during electrophysiology procedures. This method eliminates the exposure to x-ray for patients and physicians and provides optimal real-time anatomical images to guide the catheter (not relying on 3D shell rendering of the anatomy). The diagnostic catheter then confirms ablation procedure success through verification of block by pacing and sensing of the cardiac tissue[5,6].

The performance of the Vision-MR Diagnostic Catheter can be measured by comparing indirect parameters related to its use in type I atrial flutter ablation procedure including procedure success defined as demonstration of bidirectional conduction block and total procedure time. The results of the CE Mark Study for the Vision-MR Ablation Catheter, the equivalent device, demonstrate the diagnostic catheter's ability to contribute to an acute success rate of 91.4%. This acute success rate is comparable to the acute success rates reported in pre-market type I atrial flutter trials for the Navistar Thermocool Ablation Catheter (85%), Blazer Open Irrigated Ablation Catheter (87.2%) and Therapy Cool Path Ablation Catheter (92.5%). The CE Mark Study reported a total procedure time of 47.8 ± 28.1 minutes. Comparably, the Navistar Thermocool AFL IDE trial reported a total procedure time of 341.6 ± 166.9 minutes, Blazer Open Irrigated Ablation Catheter AFL trial of 98 ± 34 minutes and the Therapy Cool Path Ablation Catheter AFL trial of 133.7 ± 69 minutes. Comparison of these two indirect performance parameters demonstrates that the performance of the Vision-MR Diagnostic Catheter is in line with the state of the art.

Safety of diagnostic catheters is similar to other catheters that are manipulated in the vasculature and come in contact with the heart. As the diagnostic catheter functions do not include therapy delivery, the hazards are limited to those that would occur during navigation of the catheter within the anatomy.

2.8 Suggested Profile and Training for Users

The primary user of the device is an electrophysiologist. No additional training is required to use the Vision-MR Diagnostic Catheter.

2.9 Harmonized Standards and/or other Normative Documents

The following standards are applicable to the Vision-MR Diagnostic Catheter concerning the safety and performance of the device:

Document Identifier	Document Name
ASTM D4169-23 [E2024]	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment
ASTM F2096-11 (2019)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F2182-19e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213-17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2503-23	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ASTM F88/F88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
IEC 62366-1:2015	Medical Devices – Part 1: Application of usability engineering to medical devices
BS EN 556-2001: AC 2006	Sterilization of Medical Devices – Requirements for Medical Devices to be Designated “Sterile” – Part 1: Requirements for Terminally Sterilized Medical Devices
EN 60601-1:2006+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
BS EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
BS EN ISO 10555-1:2013+A1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements
BS EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
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 packaging systems
ISO 11607-2::2020+A1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
BS EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
BS EN 17141:2020,	Cleanrooms And Associated Controlled Environments. Biocontamination Control
ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

3. Revision History

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
A	08 April 2022	Initial Release for Notified Body submission	☐ Yes ☒ No
B	25 Aug 2022	Updates made based on technical documentation review by the Notified Body	☐ Yes ☒ No
C	27 Oct 2022	Updates made based on technical documentations review by the Notified Body	☐ Yes ☒ No
D	31 Mar 2025	Updates made to reflect current market released status of the device and updates to annual analysis of relevant literature.	☐ Yes ☒ No

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