

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)
For
ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER

Updated by: Ayça Pamukoğlu Kaynar



Reviewed and Approved by: Didem Kantar

**ALVIMEDICA ÜRÜNLER
SAN. VE TİC. A.Ş.**
İstanbul Trakya Serbest Bölgesi / Ferihatpaşa Şb.
Atatürk Bulvarı No: 16 Çarşıbaşı / İstanbul
Tel: 0212 786 60 60 Fax: 0212 786 60 90
Büyükdere V.D. 031 054 67 43
Mersis No: 0831054674800015

Date of the Report: 31.07.2025

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

Index

1	INTRODUCTION	3
2	DEVICE IDENTIFICATION AND GENERAL INFORMATION	3
3	INTENDED USE OF THE DEVICE.....	4
3.1	INTENDED PURPOSE.....	4
3.2	INDICATIONS AND TARGET POPULATION	4
3.3	CONTRAINDICATIONS AND/OR LIMITATIONS	4
4	DEVICE DESCRIPTION.....	4
4.1	DESCRIPTION OF THE DEVICE.....	4
4.2	PREVIOUS GENERATION	19
4.3	ACCESSORIES TO BE USED IN COMBINATION WITH THE DEVICE	19
4.4	OTHER DEVICES AND PRODUCTS TO BE USED IN COMBINATION WITH THE DEVICE	19
5	RISK AND WARNINGS	19
5.1	RESIDUAL RISKS AND UNDESIRABLE EFFECTS.....	19
5.2	WARNINGS AND PRECAUTIONS	20
5.3	SUMMARY OF FIELD SAFETY CORRECTIVE ACTIONS	21
6	SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF).....	21
6.1	SUMMARY OF CLINICAL DATA RELATED TO EQUIVALENT DEVICE	21
6.2	SUMMARY OF CLINICAL DATA RELATED FROM CONDUCTES INVESTIGATIONS OF THE DEVICE BEFORE CE-MARKING	22
6.3	SUMMARY OF CLINICAL DATA FROM OTHER SOURCES	22
6.4	AN OVERALL SUMMARY OF CLINICAL PERFORMANCE AND SAFETY	23
6.4.1	Evaluation of Surveys Through Product Evaluation Forms	23
6.4.2	Evaluation of The Post Market Clinical Follow-Up.....	27
6.5	ONGOING OR PLANNED POST-MARKET CLINICAL FOLLOW-UP	28
7	POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES.....	28
8	SUGGESTED PROFILE AND TRAINING FOR USERS.....	28
9	REFERENCE TO ANY HARMONISED STANDARDS AND CS (COMMON SPECIFICATION) APPLIED	29
10	REVISION HISTORY.....	34

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

1 INTRODUCTION

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The patient section is not provided as Alvision™ is not an implantable medical device and therefore not required according to MDCG 2019-9.

WARNING: The SSCP is not intended to replace the Instructions For Use (IFU) 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 healthcare professionals.

2 DEVICE IDENTIFICATION AND GENERAL INFORMATION

Trade Name: Alvision™ Interventional Cardiology Diagnostic Catheter

Manufacturer Name And Address: Alvimedica Tıbbi Ürünler Sanayi ve Dış Ticaret A.Ş. - İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi, Atatürk Bulvarı No:16 34540 Çatalca, - İstanbul, Turkey

Manufacturer's Single Registration Number (SRN): TR-MF-000029915

Basic UDI-DI: 086991955Alvision5D

MEDICAL DEVICE NOMENCLATURE

Coronary Angiography Diagnostic Catheters - EMDN Code C0104010101

Class Of Device: Class III per MDR (EU) 2017/745 Annex VIII, Rule 6.

First Certificate (CE): Alvision™ has received CE certification on 17.02.2010 under MDD 93/42/EEC by DEKRA NB number 0344.

Notified Body: ICIM S.P.A. - Piazza Don Enrico Mapelli, 7520099 - Sesto San Giovanni (MI) - Italy - Notified Body number : 0425.

MDD CE 2161507CE02 and related Addendum: issued 14th June 2018 expiration date 1st June 2023

MDD CE 2161507DE03 and related Addendum: issued 14th June 2018 expiration date 1st June 2023

0425-MDR-006771-00 EU Quality Management System Certificate issued 4th July 2023 expiration date 3rd July 2028.

0425-MDR-006772-00 EU Technical Documentation Assessment Certificate issued 4th July 2023 expiration date 3rd July 2028.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

3 INTENDED USE OF THE DEVICE

3.1 INTENDED PURPOSE

The Alvision™ Interventional Cardiology Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the coronary vascular system.

3.2 INDICATIONS AND TARGET POPULATION

Patients who are eligible for percutaneous coronary intervention (PCI).

Product should not be used in the pregnant or nursing women and pediatric patients.

3.3 CONTRAINDICATIONS AND/OR LIMITATIONS

Passing catheters through synthetic vascular grafts should be avoided

4 DEVICE DESCRIPTION

4.1 DESCRIPTION OF THE DEVICE

Alvision™ Interventional Cardiology Diagnostic Catheter Interventional Cardiology Diagnostic Catheter ("Alvision™") is single use, Ethylene Oxide (ETO) sterilized, nonpyrogenic, single lumen catheter. Different catheter configurations are available. The proximal and distal end parts are illustrated for the "selective" catheter configurations which come in a variety of tip styles and "pigtail" catheter configuration in Figure 1(a) and Figure 1(b), respectively.



Figure 1(a). Representative image of the selective catheter

For the selective catheter configurations with a soft distal tip (1), soft extension (2), body (shank) (3), a proximal strain relief (4) and luer hub (5)

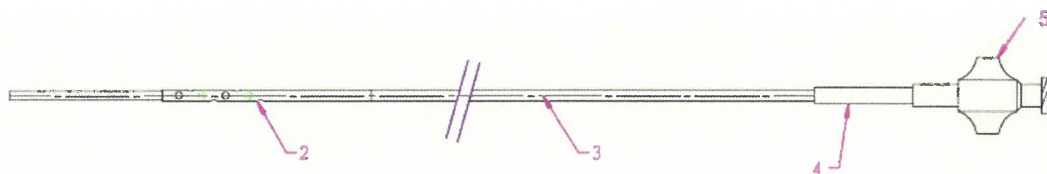


Figure 1(b). Representative image of the pigtail catheter

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

Model & Type

Table 1. Available models

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.0 4F (JL 3.0 -4F)</u>	<u>501110019601</u>	<u>501110188401</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.0 5F (JL 3.0 -5F)</u>	<u>501110019701</u>	<u>501110188501</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.0 6F (JL 3.0 -6F)</u>	<u>501110019801</u>	<u>501110188601</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.0 7F (JL 3.0 -7F)</u>	<u>501110019901</u>	<u>501110188701</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.5 4F (JL 3.5 -4F)</u>	<u>501110019602</u>	<u>501110188402</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.5 5F (JL 3.5 -5F)</u>	<u>501110019702</u>	<u>501110188502</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.5 6F (JL 3.5 -6F)</u>	<u>501110019802</u>	<u>501110188602</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 3.5 7F (JL 3.5 -7F)</u>	<u>501110019902</u>	<u>501110188702</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 4F (JL 4.0-4F)</u>	<u>501110019603</u>	<u>501110188403</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 5F (JL 4.0-5F)</u>	<u>501110019704</u>	<u>501110188503</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 6F (JL 4.0-6F)</u>	<u>501110019803</u>	<u>501110188603</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 7F (JL 4.0-7F)</u>	<u>501110019903</u>	<u>501110188703</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 SHORT TIP 4F (JL 4.0 ST -4F)</u>	<u>501110019604</u>	<u>501110188404</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 SHORT TIP 5F (JL 4.0 ST -5F)</u>	<u>501110019703</u>	<u>501110188504</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 SHORT TIP 6F (JL 4.0 ST -6F)</u>	<u>501110019804</u>	<u>501110188604</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.0 SHORT TIP 7F (JL 4.0 ST -7F)</u>	<u>501110019904</u>	<u>501110188704</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.5 4F (JL 4.5-4F)	<u>501110019605</u>	<u>501110188405</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.5 5F (JL 4.5-5F)	<u>501110019705</u>	<u>501110188505</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.5 6F (JL 4.5-6F)	<u>501110019805</u>	<u>501110188605</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 4.5 7F (JL 4.5-7F)	<u>501110019905</u>	<u>501110188705</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 5.0 4F (JL 5.0-4F)	<u>501110019606</u>	<u>501110188406</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 5.0 5F (JL 5.0-5F)	<u>501110019706</u>	<u>501110188506</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 5.0 6F (JL 5.0-6F)	<u>501110019806</u>	<u>501110188606</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 5.0 7F (JL 5.0-7F)	<u>501110019906</u>	<u>501110188706</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 6.0 4F (JL 6.0-4F)	<u>501110019607</u>	<u>501110188407</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 6.0 5F (JL 6.0-5F)	<u>501110019707</u>	<u>501110188507</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 6.0 6F (JL 6.0-6F)	<u>501110019807</u>	<u>501110188607</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS LEFT 6.0 7F (JL 6.0-7F)	<u>501110019907</u>	<u>501110188707</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.0 4F (JR 3.0-4F)	<u>501110019608</u>	<u>501110188408</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.0 5F (JR 3.0-5F)	<u>501110019708</u>	<u>501110188508</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.0 6F (JR 3.0-6F)	<u>501110019808</u>	<u>501110188608</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.0 7F (JR 3.0-7F)	<u>501110019908</u>	<u>501110188708</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.5 4F (JR 3.5-4F)	<u>501110019609</u>	<u>501110188409</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.5 5F (JR 3.5-5F)	<u>501110019709</u>	<u>501110188509</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.5 6F (JR 3.5-6F)</u>	<u>501110019809</u>	<u>501110188609</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 3.5 7F (JR 3.5-7F)</u>	<u>501110019909</u>	<u>501110188709</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.0 4F (JR 4.0-4F)</u>	<u>501110019610</u>	<u>501110188410</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.0 5F (JR 4.0-5F)</u>	<u>501110019711</u>	<u>501110188510</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.0 6F (JR 4.0-6F)</u>	<u>501110019810</u>	<u>501110188610</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.0 7F (JR 4.0-7F)</u>	<u>501110019910</u>	<u>501110188710</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.5 4F (JR 4.5-4F)</u>	<u>501110019611</u>	<u>501110188411</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.5 5F (JR 4.5-5F)</u>	<u>501110019710</u>	<u>501110188511</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.5 6F (JR 4.5-6F)</u>	<u>501110019811</u>	<u>501110188611</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 4.5 7F (JR 4.5-7F)</u>	<u>501110019911</u>	<u>501110188711</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 5.0 4F (JR 5.0-4F)</u>	<u>501110019612</u>	<u>501110188412</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 5.0 5F (JR 5.0-5F)</u>	<u>501110019712</u>	<u>501110188512</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 5.0 6F (JR 5.0-6F)</u>	<u>501110019812</u>	<u>501110188612</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 5.0 7F (JR 5.0-7F)</u>	<u>501110019912</u>	<u>501110188712</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 6.0 4F (JR 6.0-4F)</u>	<u>501110019613</u>	<u>501110188413</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 6.0 5F (JR 6.0-5F)</u>	<u>501110019713</u>	<u>501110188513</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 6.0 6F (JR 6.0-6F)</u>	<u>501110019813</u>	<u>501110188613</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter JUDKINS RIGHT 6.0 7F (JR 6.0-7F)</u>	<u>501110019913</u>	<u>501110188713</u>

**SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR
ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER****Doc No: SSCP-00001****Rev: 3**

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT I 4F (AL1 4F)</u>	<u>501110019614</u>	<u>501110188414</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT I 5F (AL1 5F)</u>	<u>501110019714</u>	<u>501110188514</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT I 6F (AL1 6F)</u>	<u>501110019814</u>	<u>501110188614</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT I 7F (AL1 7F)</u>	<u>501110019914</u>	<u>501110188714</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT II 4F (AL2 4F)</u>	<u>501110019615</u>	<u>501110188415</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT II 5F (AL2 5F)</u>	<u>501110019715</u>	<u>501110188515</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT II 6F (AL2 6F)</u>	<u>501110019815</u>	<u>501110188615</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT II 7F (AL2 7F)</u>	<u>501110019915</u>	<u>501110188715</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT III 4F (AL3 4F)</u>	<u>501110019616</u>	<u>501110188416</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT III 5F (AL3 5F)</u>	<u>501110019716</u>	<u>501110188516</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT III 6F (AL3 6F)</u>	<u>501110019816</u>	<u>501110188616</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ LEFT III 7F (AL3 7F)</u>	<u>501110019916</u>	<u>501110188716</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT I 4F (AR1 4F)</u>	<u>501110019617</u>	<u>501110188417</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT I 5F (AR1 5F)</u>	<u>501110019717</u>	<u>501110188517</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT I 6F (AR1 6F)</u>	<u>501110019817</u>	<u>501110188617</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT I 7F (AR1 7F)</u>	<u>501110019917</u>	<u>501110188717</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT II 4F (AR2 4F)</u>	<u>501110019618</u>	<u>501110188418</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT II 5F (AR2 5F)</u>	<u>501110019718</u>	<u>501110188518</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT II 6F (AR2 6F)</u>	<u>501110019818</u>	<u>501110188618</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT II 7F (AR2 7F)</u>	<u>501110019918</u>	<u>501110188718</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT III 4F (AR3 4F)</u>	<u>501110019619</u>	<u>501110188419</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT III 5F (AR3 5F)</u>	<u>501110019719</u>	<u>501110188519</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT III 6F (AR3 6F)</u>	<u>501110019819</u>	<u>501110188619</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT III 7F (AR3 7F)</u>	<u>501110019919</u>	<u>501110188719</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT MODIFIED B 4F (AR MOD B 4F)</u>	<u>501110019620</u>	<u>501110188420</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT MODIFIED B 5F (AR MOD B 5F)</u>	<u>501110019720</u>	<u>501110188520</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT MODIFIED B 6F (AR MOD B 6F)</u>	<u>501110019820</u>	<u>501110188620</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter AMPLATZ RIGHT MODIFIED B 7F (AR MOD B 7F)</u>	<u>501110019920</u>	<u>501110188720</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-LEFT 4F (LCB 4F)</u>	<u>501110019621</u>	<u>501110188421</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-LEFT 5F (LCB 5F)</u>	<u>501110019721</u>	<u>501110188521</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-LEFT 6F (LCB 6F)</u>	<u>501110019821</u>	<u>501110188621</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-LEFT 7F (LCB 7F)</u>	<u>501110019921</u>	<u>501110188721</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-RIGHT 4F (RCB 4F)</u>	<u>501110019622</u>	<u>501110188422</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-RIGHT 5F (RCB 5F)</u>	<u>501110019722</u>	<u>501110188522</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-RIGHT 6F (RCB 6F)</u>	<u>501110019822</u>	<u>501110188622</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter CORONARY BYPASS-RIGHT 7F (RCB 7F)</u>	<u>501110019922</u>	<u>501110188722</u>



SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER

Doc No: SSCP-00001

Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter INTERNAL MAMMARY 4F (IMA 4F)</u>	<u>501110019623</u>	<u>501110188423</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter INTERNAL MAMMARY 5F (IMA 5F)</u>	<u>501110019723</u>	<u>501110188523</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter INTERNAL MAMMARY 6F (IMA 6F)</u>	<u>501110019823</u>	<u>501110188623</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter INTERNAL MAMMARY 7F (IMA 7F)</u>	<u>501110019923</u>	<u>501110188723</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-1 4F (MP A-1 4F)</u>	<u>501110019624</u>	<u>501110188424</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-1 5F (MP A-1 5F)</u>	<u>501110019724</u>	<u>501110188524</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-1 6F (MP A-1 6F)</u>	<u>501110019824</u>	<u>501110188624</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-1 7F (MP A-1 7F)</u>	<u>501110019924</u>	<u>501110188724</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-2 4F (MP A-2 4F)</u>	<u>501110019625</u>	<u>501110188425</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-2 5F (MP A-2 5F)</u>	<u>501110019725</u>	<u>501110188525</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-2 6F (MP A-2 6F)</u>	<u>501110019825</u>	<u>501110188625</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE A-2 7F (MP A-2 7F)</u>	<u>501110019925</u>	<u>501110188725</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-1 4F (MP B-1 4F)</u>	<u>501110019626</u>	<u>501110188426</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-1 5F (MP B-1 5F)</u>	<u>501110019726</u>	<u>501110188526</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-1 6F (MP B-1 6F)</u>	<u>501110019826</u>	<u>501110188626</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-1 7F (MP B-1 7F)</u>	<u>501110019926</u>	<u>501110188726</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-2 4F (MP B-2 4F)</u>	<u>501110019627</u>	<u>501110188427</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-2 5F (MP B-2 5F)</u>	<u>501110019727</u>	<u>501110188527</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-2 6F (MP B-2 6F)</u>	<u>501110019827</u>	<u>501110188627</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter MULTIPURPOSE B-2 7F (MP B-2 7F)</u>	<u>501110019927</u>	<u>501110188727</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I 4F (SON 1 4F)</u>	<u>501110019628</u>	<u>501110188428</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I 5F (SON 1 5F)</u>	<u>501110019728</u>	<u>501110188528</u>
<u>ALVISION Interventional Cardiology Diagnostic Catheter SONES I 6F (SON 1 6F)</u>	<u>501110019828</u>	<u>501110188628</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I 7F (SON 1 7F)</u>	<u>501110019928</u>	<u>501110188728</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II 4F (SON 2 4F)</u>	<u>501110019629</u>	<u>501110188429</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II 5F (SON 2 5F)</u>	<u>501110019729</u>	<u>501110188529</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II 6F (SON 2 6F)</u>	<u>501110019829</u>	<u>501110188629</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II 7F (SON 2 7F)</u>	<u>501110019929</u>	<u>501110188729</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III 4F (SON 3 4F)</u>	<u>501110019630</u>	<u>501110188430</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III 5F (SON 3 5F)</u>	<u>501110019730</u>	<u>501110188530</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III 6F (SON 3 6F)</u>	<u>501110019830</u>	<u>501110188630</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III 7F (SON 3 7F)</u>	<u>501110019930</u>	<u>501110188730</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I (80 cm) 4F (SON 1 4F)</u>	<u>501110019631</u>	<u>501110188431</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I (80 cm) 5F (SON 1 5F)</u>	<u>501110019731</u>	<u>501110188531</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I (80 cm) 6F (SON 1 6F)</u>	<u>501110019831</u>	<u>501110188631</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I (80 cm) 7F (SON 1 7F)</u>	<u>501110019931</u>	<u>501110188731</u>



SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER

Doc No: SSCP-00001

Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II (80 cm) 4F (SON 2 4F)</u>	<u>501110019632</u>	<u>501110188432</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II (80 cm) 5F (SON 2 5F)</u>	<u>501110019732</u>	<u>501110188532</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II (80 cm) 6F (SON 2 6F)</u>	<u>501110019832</u>	<u>501110188632</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II (80 cm) 7F (SON 2 7F)</u>	<u>501110019932</u>	<u>501110188732</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III (80 cm) 4F (SON 3 4F)</u>	<u>501110019633</u>	<u>501110188433</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III (80 cm) 5F (SON 3 5F)</u>	<u>501110019733</u>	<u>501110188533</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III (80 cm) 6F (SON 3 6F)</u>	<u>501110019833</u>	<u>501110188633</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III (80 cm) 7F (SON 3 7F)</u>	<u>501110019933</u>	<u>501110188733</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I PP 4F (SON 1 PP 4F)</u>	<u>501110019634</u>	<u>501110188434</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I PP 5F (SON 1 PP 5F)</u>	<u>501110019734</u>	<u>501110188534</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I PP 6F (SON 1 PP 6F)</u>	<u>501110019834</u>	<u>501110188634</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES I PP 7F (SON 1 PP 7F)</u>	<u>501110019934</u>	<u>501110188734</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II PP 4F (SON 2 PP 4F)</u>	<u>501110019635</u>	<u>501110188435</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II PP 5F (SON 2 PP 5F)</u>	<u>501110019735</u>	<u>501110188535</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II PP 6F (SON 2 PP 6F)</u>	<u>501110019835</u>	<u>501110188635</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES II PP 7F (SON 2 PP 7F)</u>	<u>501110019935</u>	<u>501110188735</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III PP 4F (SON 3 PP 4F)</u>	<u>501110019636</u>	<u>501110188436</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III PP 5F (SON 3 PP 5F)</u>	<u>501110019736</u>	<u>501110188536</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III PP 6F (SON 3 PP 6F)</u>	<u>501110019836</u>	<u>501110188636</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter SONES III PP 7F (SON 3 PP 7F)</u>	<u>501110019936</u>	<u>501110188736</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL STRAIGHT (110 cm) 4F (PIG 4F)</u>	<u>501110019637</u>	<u>501110188437</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL STRAIGHT (110 cm) 5F (PIG 5F)</u>	<u>501110019737</u>	<u>501110188537</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL STRAIGHT (110 cm) 6F (PIG 6F)</u>	<u>501110019837</u>	<u>501110188637</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL STRAIGHT (110 cm) 7F (PIG 7F)</u>	<u>501110019937</u>	<u>501110188737</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 145 °(110 cm) 4F (PIG 145 4F)</u>	<u>501110019638</u>	<u>501110188438</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 145 °(110 cm) 5F (PIG 145 5F)</u>	<u>501110019738</u>	<u>501110188538</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 145 °(110 cm) 6F (PIG 145 6F)</u>	<u>501110019838</u>	<u>501110188638</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 145 °(110 cm) 7F (PIG 145 7F)</u>	<u>501110019938</u>	<u>501110188738</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 155 °(110 cm) 4F (PIG 155 4F)</u>	<u>501110019639</u>	<u>501110188439</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 155 °(110 cm) 5F (PIG 155 5F)</u>	<u>501110019739</u>	<u>501110188539</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 155 °(110 cm) 6F (PIG 155 6F)</u>	<u>501110019839</u>	<u>501110188639</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter PIGTAIL 155 °(110 cm) 7F (PIG 155 7F)</u>	<u>501110019939</u>	<u>501110188739</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) ATESAL 3.5</u>	<u>501110019641</u>	<u>501110188440</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) ATESAL 4.0</u>	<u>501110019640</u>	<u>501110188441</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) ATESAL 4.5</u>	<u>501110019642</u>	<u>501110188442</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) HOCKEY STICK</u>	<u>501110019643</u>	<u>501110188443</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) PROGRESSIVE RIGHT	<u>501110019644</u>	<u>501110188444</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) Q4	<u>501110019647</u>	<u>501110188447</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) MOD. EXTRA BACK UP	<u>501110019648</u>	<u>501110188448</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) CORONARY BYPASS GRAFT RIGHT	<u>501110019651</u>	<u>501110188451</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (100 cm) CORONARY BYPASS GRAFT LEFT	<u>501110019652</u>	<u>501110188452</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) ATESAL 3.5	<u>501110019740</u>	<u>501110188540</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) ATESAL 4.0	<u>501110019741</u>	<u>501110188541</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) ATESAL 4.5	<u>501110019742</u>	<u>501110188542</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) HOCKEY STICK	<u>501110019743</u>	<u>501110188543</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) PROGRESSIVE RIGHT	<u>501110019744</u>	<u>501110188544</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) Q4	<u>501110019747</u>	<u>501110188547</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) MOD. EXTRA BACK UP	<u>501110019748</u>	<u>501110188548</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) CORONARY BYPASS GRAFT RIGHT	<u>501110019751</u>	<u>501110188551</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) CORONARY BYPASS GRAFT LEFT	<u>501110019752</u>	<u>501110188552</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) ATESAL 3.5	<u>501110019840</u>	<u>501110188640</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) ATESAL 4.0	<u>501110019841</u>	<u>501110188641</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) ATESAL 4.5	<u>501110019842</u>	<u>501110188642</u>
ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) HOCKEY STICK	<u>501110019843</u>	<u>501110188643</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) PROGRESSIVE RIGHT</u>	<u>501110019844</u>	<u>501110188644</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) Q4</u>	<u>501110019847</u>	<u>501110188647</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) MOD. EXTRA BACK UP</u>	<u>501110019848</u>	<u>501110188648</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) CORONARY BYPASS GRAFT RIGHT</u>	<u>501110019851</u>	<u>501110188651</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) CORONARY BYPASS GRAFT LEFT</u>	<u>501110019852</u>	<u>501110188652</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) ATESAL 3.5</u>	<u>501110019941</u>	<u>501110188740</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) ATESAL 4.0</u>	<u>501110019940</u>	<u>501110188741</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) ATESAL 4.5</u>	<u>501110019942</u>	<u>501110188742</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) HOCKEY STICK</u>	<u>501110019943</u>	<u>501110188743</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) PROGRESSIVE RIGHT</u>	<u>501110019944</u>	<u>501110188744</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) Q4</u>	<u>501110019947</u>	<u>501110188747</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) MOD. EXTRA BACK UP</u>	<u>501110019948</u>	<u>501110188748</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) CORONARY BYPASS GRAFT RIGHT</u>	<u>501110019951</u>	<u>501110188751</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 7F (100 cm) CORONARY BYPASS GRAFT LEFT</u>	<u>501110019952</u>	<u>501110188752</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) JUDKINS LEFT 6.0</u>	<u>501110019501</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) JUDKINS LEFT 4.0</u>	<u>501110019502</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) JUDKINS LEFT 5.0</u>	<u>501110019503</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) JUDKINS RIGHT 4.0</u>	<u>501110019504</u>	<u>NA</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) JUDKINS RIGHT 5.0</u>	<u>501110019505</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) JUDKINS RIGHT 6.0</u>	<u>501110019506</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) PIGTAIL 145 °</u>	<u>501110019519</u>	<u>NA</u>
<u>ALVISION Interventional Cardiology Diagnostic Catheter 4F (125 cm) PIGTAIL 155 °</u>	<u>501110019520</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 4F (125 cm) PIGTAIL STRAIGHT</u>	<u>501110019525</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) JUDKINS LEFT 4.0</u>	<u>501110019507</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) JUDKINS LEFT 5.0</u>	<u>501110019508</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) JUDKINS LEFT 6.0</u>	<u>501110019509</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) JUDKINS RIGHT 4.0</u>	<u>501110019510</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) JUDKINS RIGHT 5.0</u>	<u>501110019511</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) JUDKINS RIGHT 6.0</u>	<u>501110019512</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) PIGTAIL 145 °</u>	<u>501110019521</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) PIGTAIL 155 °</u>	<u>501110019522</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (125 cm) PIGTAIL STRAIGHT</u>	<u>501110019526</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) JUDKINS LEFT 4.0</u>	<u>501110019513</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F(125 cm) JUDKINS LEFT 5.0</u>	<u>501110019514</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) JUDKINS LEFT 6.0</u>	<u>501110019515</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) JUDKINS RIGHT 4.0</u>	<u>501110019516</u>	<u>NA</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) JUDKINS RIGHT 5.0</u>	<u>501110019517</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) JUDKINS RIGHT 6.0</u>	<u>501110019518</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) PIGTAIL 145 °</u>	<u>501110019523</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) PIGTAIL 155 °</u>	<u>501110019524</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (125 cm) PIGTAIL STRAIGHT</u>	<u>501110019527</u>	<u>NA</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN 4.0 PP</u>	<u>501110019301</u>	<u>501110188801</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN 4.5 PP</u>	<u>501110019302</u>	<u>501110188802</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN MOD I 4.0 PP</u>	<u>501110019786</u>	<u>501110188586</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN MOD I 4.5 PP</u>	<u>501110019787</u>	<u>501110188587</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN MOD I 5.0 PP</u>	<u>501110019890</u>	<u>501110188690</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN MOD II 4.0 PP</u>	<u>501110019886</u>	<u>501110188686</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN MOD II 4.5 PP</u>	<u>501110019887</u>	<u>501110188687</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN MOD II 5.0 PP</u>	<u>501110019891</u>	<u>501110188691</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN JS 3.5 PP</u>	<u>501110019304</u>	<u>501110188804</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (100 cm) KAPLAN JS 4.0 PP</u>	<u>501110019303</u>	<u>501110188803</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN 4.0 PP</u>	<u>501110019309</u>	<u>501110188809</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN 4.5 PP</u>	<u>501110019310</u>	<u>501110188810</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN MOD I 4.0 PP</u>	<u>501110019893</u>	<u>501110188693</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN MOD I 4.5 PP</u>	<u>501110019894</u>	<u>501110188694</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN MOD I 5.0 PP</u>	<u>501110019892</u>	<u>501110188692</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN MOD II 4.0 PP</u>	<u>501110019896</u>	<u>501110188696</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN MOD II 4.5 PP</u>	<u>501110019897</u>	<u>501110188697</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN MOD II 5.0 PP</u>	<u>501110019895</u>	<u>501110188695</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN JS 3.5 PP</u>	<u>501110019312</u>	<u>501110188812</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 5F (110 cm) KAPLAN JS 4.0 PP</u>	<u>501110019311</u>	<u>501110188811</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN 4.0 PP</u>	<u>501110019305</u>	<u>501110188805</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN 4.5 PP</u>	<u>501110019306</u>	<u>501110188806</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN MOD I 4.0 PP</u>	<u>501110019888</u>	<u>501110188688</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN MOD I 4.5 PP</u>	<u>501110019889</u>	<u>501110188689</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN MOD I 5.0 PP</u>	<u>501110019790</u>	<u>501110188590</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN MOD II 4.0 PP</u>	<u>501110019788</u>	<u>501110188588</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN MOD II 4.5 PP</u>	<u>501110019789</u>	<u>501110188589</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN MOD II 5.0 PP</u>	<u>501110019791</u>	<u>501110188591</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN JS 3.5 PP</u>	<u>501110019308</u>	<u>501110188808</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (100 cm) KAPLAN JS 4.0 PP</u>	<u>501110019307</u>	<u>501110188807</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN 4.0 PP</u>	<u>501110019313</u>	<u>501110188813</u>

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

<u>Product Description</u>	<u>5 Pack Code</u>	<u>10 Pack Code</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN 4.5 PP</u>	<u>501110019314</u>	<u>501110188814</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN MOD I 4.0 PP</u>	<u>501110019793</u>	<u>501110188593</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN MOD I 4.5 PP</u>	<u>501110019794</u>	<u>501110188594</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN MOD I 5.0 PP</u>	<u>501110019792</u>	<u>501110188592</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN MOD II 4.0 PP</u>	<u>501110019796</u>	<u>501110188596</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN MOD II 4.5 PP</u>	<u>501110019797</u>	<u>501110188597</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN MOD II 5.0 PP</u>	<u>501110019795</u>	<u>501110188595</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN JS 3.5 PP</u>	<u>501110019316</u>	<u>501110188816</u>
<u>ALVISION™ Interventional Cardiology Diagnostic Catheter 6F (110 cm) KAPLAN JS 4.0 PP</u>	<u>501110019315</u>	<u>501110188815</u>

4.2 PREVIOUS GENERATION

NOT APPLICABLE

4.3 ACCESSORIES TO BE USED IN COMBINATION WITH THE DEVICE

Alvision™ Interventional Cardiology Diagnostic Catheter does not contain separate components/ accessories, is not sold as part of a kit.

4.4 OTHER DEVICES AND PRODUCTS TO BE USED IN COMBINATION WITH THE DEVICE

Compatible catheter sheath introducer (CSI) and guidewire (max. 0.038").

5 RISK AND WARNINGS

5.1 RESIDUAL RISKS AND UNDESIRABLE EFFECTS

The following adverse reactions have been reported to be associated with the use of diagnostic catheters: thrombus formation/emboli, arterial wall damage, plaque dislodgement, myocardial infarction, cardiac arrhythmia, stroke and death.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

Physicians should be familiar with the current literature concerning the complications associated with angiography.

Possible adverse events include:

- Air embolism
- Hematoma
- Infection
- Perforation of the heart or vessel wall

5.2 WARNINGS AND PRECAUTIONS

- Diagnostic catheters are invasive devices that pose a potential risk of injury or death.
- Accordingly, angiographic catheters should only be used by trained, experienced physicians who are aware of the potential complications and risks of angiography.
- Extreme care must be taken to avoid causing damage to the vessel walls through which the catheter passes.
- This catheter may occlude smaller vessels.
- Take care to avoid completely blocking the blood flow.
- Do not reuse or reshape the catheter.
- The maximum permitted diameter of the guidewire is specified on the pouch. Guidewire use has been associated with thrombus formation.
- Alvion™ Interventional Cardiology Diagnostic Catheters are intended for single use only and should be disposed of after one procedure.
- Do not allow catheters to come into contact with organic solvents.
- Do not pressurize catheters to in excess of the rated maximum pressure marked on the pouch label.
- A thorough inspection should be made to verify whether the size, shape and condition of the catheter are suitable for the procedure concerned.
- Angiography should only be performed by an experienced physician. Catheters are supplied sterile and non-pyrogenic.
- Do not use if the package has been opened or damaged.
- As with any surgical procedure, it is recommended to apply "Universal Precautions".
- Avoid damaging the tip of the catheter during removal from the packaging.
- Removing too rapidly may result in damage to the catheter tip.
- Take care to prevent or reduce clotting when using a catheter.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

- Whilst in the vascular system, the catheter should always be filled with either flushing solution or contrast medium.
- The use of systemic heparinization should be considered.
- These catheters are designed for use in the injection of contrast media as well as to facilitate physiological measurement in conjunction with routine diagnostic procedures.
- Do not use after the “Use By” date specified on the label.
- Do not expose catheters to strong solvents or ionizing radiation.
- Do not store in excessive heat.
- Avoid prolonged exposure to UV light.
- Do not re-use, re-process or re-sterilize. This will affect the product performance. The product may not be able to withstand the stresses of re-use. Cleaning or re-processing of the catheter components exposed to biological materials may result in adverse device effect when used.
- If a serious incident related to device occurs, immediately report the incident to Alvimedica and applicable competent authority or regulatory body.

The product might be a potential biohazard, after use. Handling and dispose of products in accordance with accepted medical practice, applicable local laws and regulations must be done and is not in the responsibility of Alvimedica.

- The Summary of Safety and Clinical Performance (SSCP) for this device can be found at Alvimedica web site www.alvimedica.com and in EUDAMED database when available.

5.3 SUMMARY OF FIELD SAFETY CORRECTIVE ACTIONS

No field safety corrective actions have been taken. In particular, we haven't received any field safety notices nor general safety information.

6 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

6.1 SUMMARY OF CLINICAL DATA RELATED TO EQUIVALENT DEVICE

The concept of equivalence has not been applied to any other medical devices available on the market.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

6.2 SUMMARY OF CLINICAL DATA RELATED FROM CONDUCTES INVESTIGATIONS OF THE DEVICE BEFORE CE-MARKING

6.2.1. Pre-market clinical investigation

There is no pre-market clinical investigation was conducted on the Alvision™ Interventional Cardiology Diagnostic Catheter but from the time since 17.02.2010 Alvision™ Interventional Cardiology Diagnostic Catheter has been available on the market the overall assessment from the users is always shows good performing with a high market satisfaction/low customer complaint ratio.

6.2.2. Relevant pre-clinical studies

Pre-clinical tests

The preclinical evaluation of the device with the proposed modifications was performed in order to assess the safety and the efficacy.

Bench tests

In vitro performance of Alvision catheters are evaluated by visual inspection, useable catheter length, trackability, torquability etc. according to the relevant each Design Verification Protocols. All the test results are found within tolerances and acceptable as stated in the related each Design Verification Reports. All the list of the bench tests are stated in the Technical File of Alvision with the code STED-MDR-00001.

6.3 SUMMARY OF CLINICAL DATA FROM OTHER SOURCES

As specified in the Clinical Evaluation Procedure and the Clinical Evaluation Plan, the literatures obtained are evaluated and eliminated within the scope of the inclusion/exclusion criteria (MEDDEV 2.7/1 Rev.4, 2016). So within this scope The Clinical Researcher conducted the literature search and analyzed the literature data in the document with the code DVA-00544 Clinical Evaluation Report of Alvision™ Interventional Cardiology Diagnostic Catheter. According to this report the final result is shown as in the below Table 2.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

Table 2. Literature Database Results

Total Literature	Database			Exclusion Criteria	Inclusion Criteria
	PubMed	Cochrane Library	ScienceDirect		
1962	1542	420	0	1945	17

After the literature search in the last 3 years the detailed evaluation is performed according to MDCG 2020-6. Almost all literature is at Level 1, this situation shows that the relevant literatures are selected and eliminated with the right strategy. So this result shows our clinical evidence is strong with the selection of keywords related to the product, the number of literatures obtained, and the number of literatures eliminated. No adverse events, feedback or risks were encountered in the literature regarding our product and equivalent products stated during literature search. As a result of these comprehensive studies have provided valuable information about the performance and safety features of the device. Importantly, no article has shown significant differences in clinical outcome.

6.4 AN OVERALL SUMMARY OF CLINICAL PERFORMANCE AND SAFETY

6.4.1 Evaluation of Surveys Through Product Evaluation Forms

The PEFs are collected customers' satisfaction grade, classified from poor to excellent in five steps, for the device features, including the overall performance and usability. A score ranging from 1 to 5 has been assigned to each evaluation, and the average score has been calculated. Furthermore, per each feature, the Customer Satisfaction Score (CSS) has also been calculated, which is the percentage of customers assigning an Above average or Average grade.

The surveys' results in the last 3 years are represented from the below tables & graphs:

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

Table 3. Table of PEFs scores for 2024

	<u>Stable positioning</u> (n=15)		<u>Torque control</u> (n=15)		<u>Shaft pushability</u> (n=15)		<u>Kink resistance</u> (n=15)		<u>Tip atraumaticity</u> (n=15)		<u>Catheter/tip radiopacity</u> (n=15)		<u>Flow Rate</u> (n=15)		<u>Overall performance</u> (n=15)		<u>Usability</u> (n=15)	
	N	%	N	%	N	%	N	%	N	%	N	%	0	0%	0	0%	0	0%
<u>Excellent</u>	1	6.66%	1	6.66%	1	6.66%	1	6.66%	1	6.66%	1	6.66%	4	26.6%	1	6.66%	4	26.6%
<u>Above average</u>	6	40%	5	33.3%	5	33.3%	5	33.3%	6	40%	5	33.3%	4	26.6%	6	40%	6	40%
<u>Average</u>	8	53.3%	9	60%	8	53.3%	8	53.3%	8	53.3%	8	53.3%	7	46.6%	8	53.3%	5	33.3%
<u>Below Av</u>	0	0.0%	0	0.0%	1	6.66%	1	6.66%	0	0%	1	6.66%	0	0.0%	0	0.0%	0	0.0%
<u>Poor</u>	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0%	0	0%	0	0%
<u>Customer Satisfaction score</u>	93.3%		93.3%		86.6%		86.6%		93.3%		86.6%		73.2%		93.3%		73.3%	

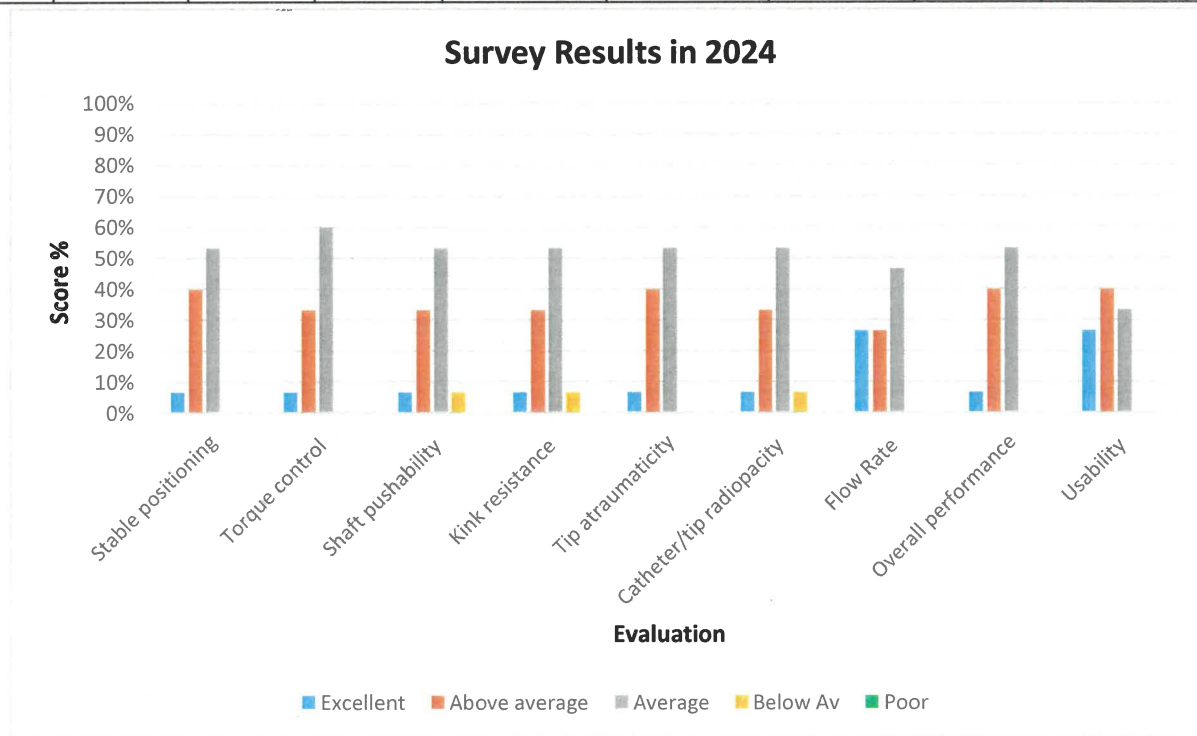


Figure 2. Graphs of PEFs scores for 2024

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER									
	Doc No: SSCP-00001					Rev: 3				

Table 4. Table of PEFs scores for 2023

	Stable positioning (n=10)		Torque control (n=10)		Shaft pushability (n=10)		Kink resistance (n=10)		Tip atraumaticity (n=10)		Catheter/tip radiopacity (n=10)		Flow Rate (n=10)		Overall performance (n=10)		Usability (n=10)	
	N	%	N	%	N	%	N	%	N	%	N	%	0	0%	0	0%	0	0%
Excellent	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	2	20%	0	0%	2	20%
Above average	5	50%	2	20%	7	70%	6	60%	6	60%	5	50%	5	50%	6	60%	5	50%
Average	4	40%	7	70%	3	30%	4	40%	3	30%	5	50%	3	30%	3	30%	3	30%
Below Av	1	10%	1	10%	0	0.0%	0	0.0%	1	10%	0	0.0%	0	0.0%	1	10%	0	0.0%
Poor	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0%	0	0%	0	0%
Customer Satisfaction score	90%		90%		100%		100%		90%		100%		80%		90%		80%	

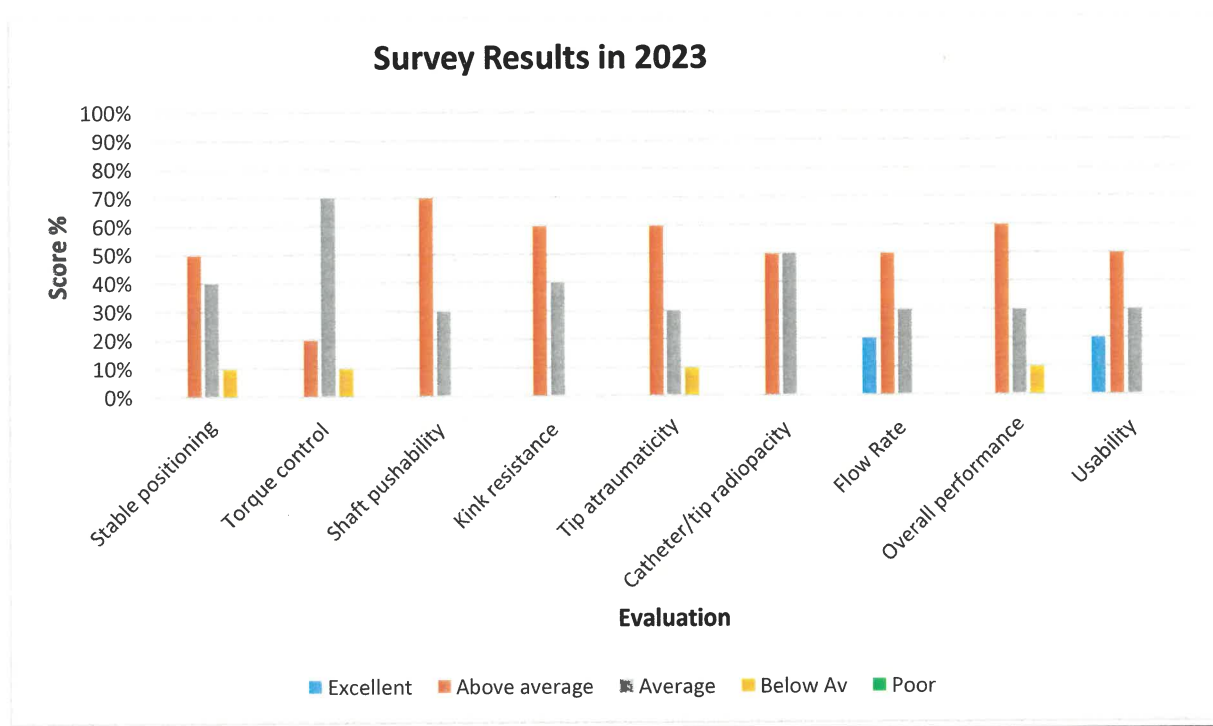


Figure 3. Graphs of PEFs scores for 2023

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER									
	Doc No: SSCP-00001					Rev: 3				

Table 5. Table of PEFs scores for 2022

	Stable positioning (n=18)		Torque control (n=18)		Shaft pushability (n=18)		Kink resistance (n=18)		Tip atraumaticity (n=18)		Catheter/tip radiopacity (n=18)		Flow Rate (n=18)		Overall performance (n=18)		Usability (n=18)	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Excellent	4	22.2%	5	27.8%	4	22.2%	3	16.7%	0	0.0%	5	27.8%	5	27.8%	5	27.8%	5	27.8%
Above average	8	44.4%	6	33.3%	8	44.4%	8	44.4%	10	55.6%	7	38.9%	7	38.9%	7	38.9%	7	38.9%
Average	5	27.8%	6	33.3%	6	33.3%	6	33.3%	7	38.9%	6	33.3%	6	33.3%	6	33.3%	6	33.3%
Below Av	1	5.6%	1	5.6%	0	0.0%	1	5.6%	1	5.6%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Poor	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Customer Satisfaction score	66.6		61.1		66.6		61.1		55.6		66.7		66.7		66.7		66.7	

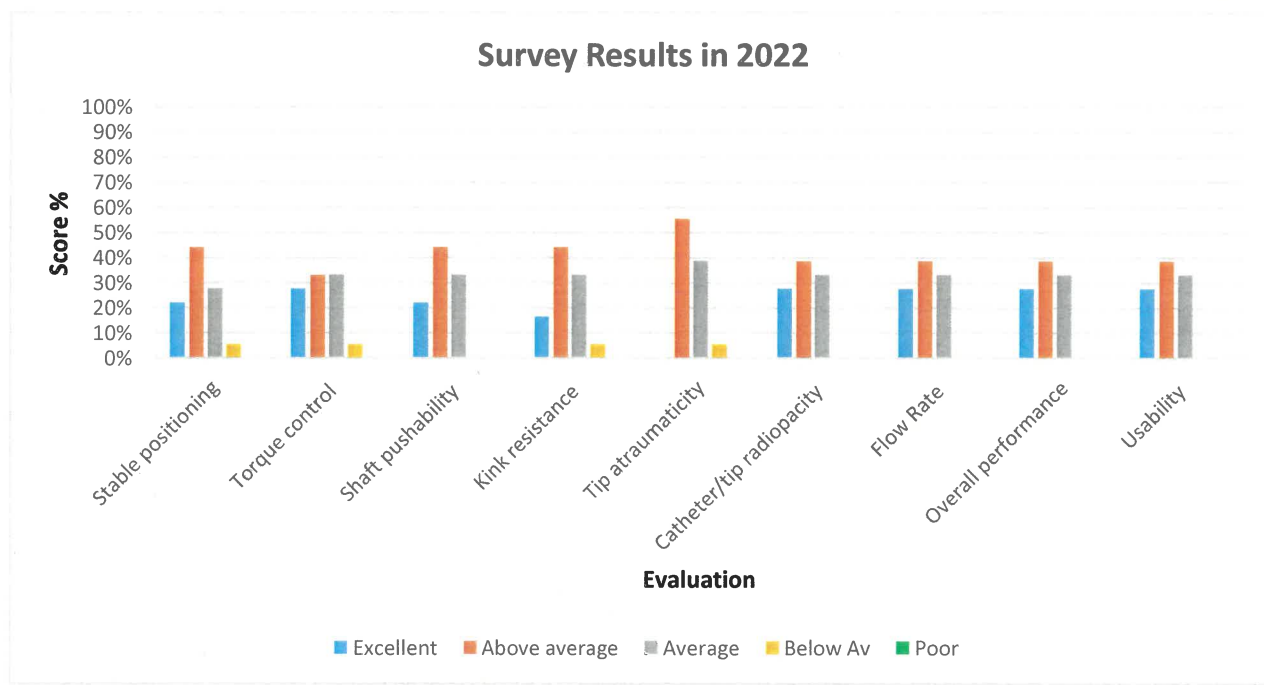


Figure 4. Graphs of PEFs scores for 2022

Conclusion: According to the overall evaluation for the latest 3 years results between 2022-2024 indicates that Alvion™ is a safe and effective product with a good satisfactory rate given by the customers.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

6.4.2 Evaluation of The Post Market Clinical Follow-Up

Study title

Alvision™ Interventional Cardiology Diagnostic Catheter Use for Routine Diagnostic Procedures in Angiographic Applications: Evaluation of Safety and Performance in Everyday Clinical Practice. The Alvision™ Interventional Cardiology Diagnostic Catheter Post Market Clinical Follow-up (PMCF) Study.

Objective

The objective of this prospective observational study is to collect clinical data on the medical device Alvision™ Interventional Cardiology Diagnostic Catheter in an unselected population in the current clinical practice.

Study Design

This present study is a prospective observational study to collect real-world data on the non-implantable medical device Alvision™ Interventional Cardiology Diagnostic Catheter in an unselected population in the current clinical practice.

Sample Size

Due to the observational nature of the study, no statistical hypothesis is applicable and, therefore, no sample size calculation was performed. A number of 100 enrolled subjects was estimated to provide enough information to evaluate the objective of the study.

Safety of device

No complications occurred in the patients. Seventy-five patients were discharged within 24 hours, while 5 remained hospitalized for follow-up. Regarding cardiac status all patients were asymptomatic at discharge. None of the patients experienced major adverse cardiovascular events (MACEs) and stroke associated with the use of diagnostic catheters.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

	N=100	n (%)
Any complication?	No	100 (100.0)
	Yes	0 (0.0)
Discharge Status	Discharged	92 (92.0)
	Hospitalization (After 24- hours follow-up)	8 (8.0)
If not discharged at 24 hours, the reason for in-hospital stay	Follow-up	8 (100.0)
Cardiac status at discharge	Asymptomatic	100 (100.0)

Conclusion

The results of report of the observational study on real life data of 100 patients confirm the safety and efficacy of Alvion™ Interventional Cardiology Diagnostic Catheters. The successful insertion of the catheter was obtained in 99% of the patients. All of the key features of the device received very high ratings from the users: 99% of the procedures received a rate of excellent or above average for torquability and slippage, and 98% for trackability. Moreover, it is a safe tool as none of the patients experienced MACEs, stroke or complications during or after the procedure.

6.5 ONGOING OR PLANNED POST-MARKET CLINICAL FOLLOW-UP

Given the extensive experience with the device since its launch and the findings from Alvion™ Interventional Cardiology Diagnostic Catheter PMCF study, which shows that the device is performing well with no cause for concern, we believe that no further post-market clinical study is needed.

The proactive collection of Customer Feedback via Performance Evaluations Forms (PEFs) specifically designed continues throughout the product life.

7 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

The use of coronary angiography diagnostic catheters is a well-established practice since the introduction of the coronary angiography, and no valid alternative is available.

8 SUGGESTED PROFILE AND TRAINING FOR USERS

Diagnostic catheters are invasive devices that pose a potential risk of injury or death. Accordingly, angiographic catheters should only be used by trained, experienced physicians who are aware of the potential complications and risks of angiography.

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

9 REFERENCE TO ANY HARMONISED STANDARDS AND CS (COMMON SPECIFICATION) APPLIED

Table 6. List of Applicable Standards

STANDARD CODE	STANDARD NAME
EN ISO 10993-1:2020	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing With A Risk Management Process (Iso 10993-1:2018, Including Corrected Version 2018-10)
EN ISO 10993-4 V2:2017	Biological Evaluation Of Medical Devices - Part 4: Selection Of Tests For Interactions With Blood (Iso 10993-4:2017)
EN ISO 10993-5:2009	Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity (Iso 10993-5:2009)
EN ISO 10993-6:2016	Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation (Iso 10993-6:2016)
EN ISO 10993-7:2008/ AMD1:2019	Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals - Amendment 1: Applicability Of Allowable Limits For Neonates And Infants (Iso 10993-7:2008/Amd.1:2019)
EN ISO 10993-10:2021	Biological Evaluation Of Medical Devices - Part 10: Tests For Skin Sensitization (Iso 10993-10:2021)
EN ISO 10993-11:2018	Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity (Iso 10993-11:2017)
EN ISO 10993-12:2021	Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials (Iso 10993-12:2021)
ISO 10993-18:2020	Biological Evaluation Of Medical Devices - Part 18: Chemical Characterization Of Medical Device Materials Within A Risk Management Process
ISO 10993-15:2019	Biological Evaluation Of Medical Devices - Part 15: Identification And Quantification Of Degradation Products From Metals And Alloys
ISO 10993-23:2021	Biological Evaluation Of Medical Devices - Part 23: Tests For Irritation

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

STANDARD CODE	STANDARD NAME
EN ISO 11135:2014/ A1:2019	Sterilization Of Health Care Products - Ethylene Oxide Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices Amendment 1: Revision Of Annex E, Single Batch Release (Iso 11135:2014/Amd 1:2018)
EN ISO 11737-1:2018	Sterilization Of Health Care Products - Microbiological Methods - Part 1: Determination Of A Population Of Microorganisms On Products (Iso 11737-1:2018)
EN ISO 11737-2:2020	Sterilization Of Health Care Products - Microbiological Methods - Part 2: Tests For Sterility Performed In The Definition, Validation And Maintenance Of Sterilization Process (Iso 11737-2:2019) / 2020
EN ISO 11607-1:2020	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems (Iso 11607-1:2007 Including Amd 1:2014)
EN ISO 11607-2 :2020	Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes (Iso 11607-2:2007 Including Amd 1:2014)
EN 868-2:2017	Packaging For Terminally Sterilized Medical Devices - Part 2: Sterilization Wrap Requirements And Test Methods
EN 868-4:2017	Packaging For Terminally Sterilized Medical Devices - Part 4: Paper Bags Requirements And Test Methods
EN 868-5:2018	Packaging For Terminally Sterilized Medical Devices - Part 5: Sealable Pouches And Reels Of Porous Materials And Plastic Film Construction - Requirements And Test Methods
EN 868-6:2017	Packaging For Terminally Sterilized Medical Devices - Part 6: Paper For Low Temperature Sterilization Processes - Requirements And Test Methods
EN ISO 15223-1:2021	Medical Devices - Symbols To Be Used With Information To Be Supplied By The Manufacturer - Part 1: General Requirements (Iso 15223-1:2021)
EN ISO 14644-1:2015	Cleanrooms And Associated Controlled Environments - Part 1: Classification Of Air Cleanliness By Particle Concentration (Iso 14644-1:2015)

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

STANDARD CODE	STANDARD NAME
EN 1041:2008+A1:2013	Information Supplied By The Manufacturer Of Medical Devices
EN ISO 11070:2014	Sterile Single-Use Intravascular Introducers, Dilators And Guidewires (Iso 11070:2014)
EN ISO 14644-2: 2015	Cleanrooms And Associated Controlled Environments - Part 2: Monitoring To Provide Evidence Of Cleanroom Performance Related To Air Cleanliness And Particle Concentration (Iso 14644-2:2015)
EN ISO 14644-3: 2019	Cleanrooms And Associated Controlled Environments - Part 3: Test Methods (Iso 14644-3:2019)
EN ISO 13485:2016 A11:2021	Medical Devices. Quality Management Systems - Requirements For Regulatory Purposes (Iso 13485:2016)
EN ISO 14971:2019-A11 2021	Medical Devices — Application Of Risk Management To Medical Devices
ISO 24971:2020	Medical Devices — Guidance On The Application Of Iso 14971
EN 556-1:2001/AC:2006	Sterilization Of Medical Devices - Requirements For Medical Devices To Be Designated "Sterile" – Part 1: Requirements For Terminally Sterilized Medical Devices
EN ISO 10555 -1:2013/ A1: 2017	Intravascular Catheters – Sterile And Single-Use Catheters - Part 1: General Requirements – Amendment 1 (Iso 10555-1:2013/ Amd 1:2017)
EN ISO 14155:2020	Clinical Investigation Of Medical Devices For Human Subjects – Good Clinical Practice
EN ISO 80369-7:2021	Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular Or Hypodermic Applications
EN ISO/IEC 17050-1 :2010	Conformity Assessment - Supplier's Declaration Of Conformity - Part 1: General Requirements (En Iso/Iec 17050-1:2004, Corrected Version 2007-06-15)
EN ISO/IEC 17050-2:2004	Conformity Assessment - Supplier's Declaration Of Conformity - Part Supporting Documentation (Iso/Iec 17050-2:2004)
EN ISO 11138-1:2017	Sterilization Of Health Care Products - Biological Indicators - Part 1: General Requirements (Iso 11138-1:2017)

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

STANDARD CODE	STANDARD NAME
EN ISO 11138-2:2017	Sterilization Of Health Care Products - Biological Indicators - Part 2: Biological Indicators For Ethylene Oxide Sterilization Processes (Iso 11138-2:2017)
EN ISO 11138-7:2019	Sterilization Of Health Care Products - Biological Indicators - Part 7: Guidance For The Selection, Use And Interpretation Of Results (Iso 11138-7:2019)
EN ISO 14937:2009	Sterilization Of Health Care Products - General Requirements For Characterization Of A Sterilizing Agent And The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices (Iso 14937:2009)
EN ISO 11139:2018	Sterilization Of Health Care Products - Vocabulary - Terms Used In Sterilization And Related Equipment And Process Standards (Iso 11139:2018) / 2018
EN 17141:2020	Cleanrooms And Associated Controlled Environments - Biocontamination Control
EN 62366-1:2015	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
MEDDEV 2.7/1 REV.4	Clinical Evaluation A Guide For Manufacturers And Notified Bodies Under Directives
MEDDEV 2.12/1 REV.8	Guidelines On A Medical Devices Vigilance System
MEDDEV 2.12-2 REV2	-Up Studies
MEDDEV 2.5/5 REV.3	Translation Procedure
GHTF-SG2-N54R8 2006	Medical Devices Post Market Surveillance: Global Guidance For Adverse Event Reporting For Medical Devices
GHTF-SG3-N15R8 2005	Implementation Of Risk Management Principles And Activities Within A Quality Management System
GMP-ANNEX I	Gmp-Annex I -Manufacture Of Sterile Medicinal Products (Corrected Version)
ASTM D5276-19	Standard Test Method For Drop Test Of Loaded Containers By Free Fall / 2019
ASTM E122 - 17	Standard Practice For Calculating Sample Size To Estimate, With Specified Precision, The Average For A Characteristic Of A Lot Or Process / 2017
ASTM E29-19	Standard Practice For Using Significant Digits In Test Data To Determine Conformance With Specifications / 2019
ASTM F 756-00	Standard Practice For Assessment Of Hemolytic Properties Of Materials / 2000

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

STANDARD CODE	STANDARD NAME
ASTM F1886 F1886M - 16	Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection / 2016
ASTM F1929 - 15	Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration/2015
ASTM F1980 - 16	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices / 2016
ASTM F2096 - 11	Standard Test Method For Detecting Gross Leaks In Packaging By Internal Pressurization (Bubble Test) / 2011
ASTM F2475-20	Standard Guide For Biocompatibility Evaluation Of Medical Device Packaging Materials / 2020
ASTM F640 - 12	Standard Test Methods For Determining Radiopacity For Medical Use / 2012
ASTM F88 F88M - 15	Standard Test Method For Seal Strength Of Flexible Barrier Materials / 2015
ASTM F640 – 20	Standard Test Methods For Determining Radiopacity For Medical Use
ISO 11138-8 / 2021	Sterilization Of Health Care Products — Biological Indicators Part 8: Method For Validation Of A Reduced Incubation Time For A Biological Indicator
Medical Device Directive	Medical Device Directive 93/42/EEC As Amended By 2007/47/EC
Medical Device Regulation Regulation	(EU) 2017/745 Of The European Parliament And Of The Council Of 5 April 2017 On Medical Devices
MDCG-2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies - March 2022

	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) FOR ALVISION™ INTERVENTIONAL CARDIOLOGY DIAGNOSTIC CATHETER	
	Doc No: SSCP-00001	Rev: 3

10 REVISION HISTORY

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
0	30.09.2022	New Document	N.A
1	27.06.2023	Par. 2 inserted previous reference to MDD CE	N.A
2	24.05.2024	- TR-MF-000029915 - 086991955InvaderPTCAVA -0425-MDR-006772-00 EU Quality Management System Certificate issued 4 th July 2023 expiration date 3 rd July 2028. -0425-MDR-006773-00 EU Technical Documentation Assessment Certificate issued 4 th July 2023 expiration date 3 rd July 2028.	NA
<u>3</u>	<u>31.07.2025</u>	<u>PSUR, PMCF ve CER</u> <u>kapsamıyla uyumlu olacak</u> <u>şekilde tüm bölümleri</u> <u>gözden geçirilerek revize</u> <u>edilmiştir. Bu nedenle,</u> <u>revizyonlar ayrıca altı</u> <u>çizilerek belirtilmemiştir. /</u> <u>All sections have been</u> <u>reviewed and revised to</u> <u>ensure compliance with</u> <u>PSUR, PMCF and CER.</u> <u>Therefore, the revisions</u> <u>have not been highlighted.</u>	<u>NA</u>