DECLARATION OF CONFORMITY

(check all additional conformity route(s) based on EU MDD Article 11 requirements for the device class and specifics)

Annex II (4) ☐ Annex V ☐ Annex III ☐

Annex II (3) ☒ Annex VI ☐ Annex IV ☐

Annex VII ☐

Technical File Number: FW-SG-044

Device Trade Name: Alcon Incisional Instruments

Supersedes (Date): 16-Feb-2021

Manufacturer: Alcon Laboratories, Incorporated

Address: 6201 South Freeway, Fort Worth, TX 76134-2099, USA

Authorized Representative in the European Community:

Alcon Laboratories Belgium

Address:
Lichterveld 3
2870 Puurs-Sint-Amands, Belgium

Device (Trade Name)	GMDN Code & Term	Model/Catalogue Number	Risk Class
Alcon Incisional Instruments	46741 Ophthalmic knife, single-use	See attached	IIa

Basic UDI-DI Group Name	Basic UDI-DI Product Name	Basic UDI-DI Number
Alcon Incisional Cutting Instruments	Slit Knives	038065GMN000019GY
	Crescent Knives	038065GMN000028GZ
	Implant Knives	038065GMN000021GK
	Standard Angle Knives	038065GMN000022GM
	Disc Knives	038065GMN000023GP
	V-Lance Knives	038065GMN000024GR
	Sideport Knives	038065GMN000029H3
	Alcon Surgical Blades	038065GMN000026GV
Alcon Incisional Safety Knives	Slit Knives	038065GMN000027GX
	Crescent Knives	038065GMN000020GH
	Sideport Knives	038065GMN000025GT

The device(s) covered by this declaration are in conformity with the European Medical Devices Directive 93/42/EEC as well as other, relevant Union legislation that make provisions for the issuing of a declaration of conformity as listed.

Alcon Laboratories, Incorporated. hereby declares under its sole responsibility that the listed device(s) and Quality Systems

Alcon Incisional Instruments, FW-SG-044

conform(s) to:

EU MDD 93/42/EEC *as amended*

This Declaration is applicable to all products listed and released after the Date of Issuance of this Declaration of Conformity, and until a revised Declaration of Conformity is issued.

Notified Body Information: Applicable ☒ Not Applicable ☐

Conformity Assessment Certificate Number(s): G1 020895 0393, Revision 00

Conformity Certificate Validity Period: 05-Feb-2021 to 26-May-2024

Notified Body: TÜV SÜD Product Service GmbH

Identification number: 0123

Address: Ridlerstraße 65 80339 München, Germany

Regulations, Directives and Standards Applied: Refer to Section 4 of the Technical Documentation

Place of Issue:	Lemke, Sylvia Digitally signed by Lemke, Sylvia DN: cn=Lemke, Sylvia, ou=PDF Internal Signing, o=Alcon Vision, LLC Reason: I am approving this document Date: 2021.05.25 17:12:33 -07'00' Adobe Acrobat DC version: 2015.006.30503
Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Sylvia Lemke, Senior Director, Global Regulatory Affairs

Alcon Incisional Cutting Instruments by Type, Group and Sub-group				
Product Type	**Product Group**	**Product Sub-Group**	**Part Number**	**Description**
Slit Knives	A-OK^	A-OK^ SATINSLIT	8065992561	SATINSLIT 2.5 mm Angled Slit Knife
			8065992761	SATINSLIT 2.75 mm Angled Slit Knife
			8065992961	SATINSLIT 3.0 mm Angled Slit Knife
			8065993261	SATINSLIT 3.2 mm Angled Slit Knife
	I-KNIFE# II Tips and Blades	I-KNIFE# II SATINSLIT Tips and Blades	8065992762	I-KNIFE II 2.75 mm Angled SATINSLIT
			8065992962	I-KNIFE II 3.0 mm Angled SATINSLIT
	CLEARCUT	INTREPID Micro-coaxial System (Single Bevel)	8065991845	CLEARCUT INTREPID Micro-Coaxial System Single Bevel 1.8 mm Slit Knife
			8065992045	CLEARCUT INTREPID Micro-Coaxial System Single Bevel 2.0 mm Slit Knife
			8065992245	CLEARCUT INTREPID Micro-Coaxial System Single Bevel 2.2 mm Slit Knife
			8065992445	CLEARCUT INTREPID Micro-Coaxial System Single Bevel 2.4 mm Slit Knife
		INTREPID Micro-coaxial System (Dual Bevel)	8065981865	CLEARCUT HP² INTREPID Micro-Coaxial system Dual Bevel 1.8 mm Slit Knife
			8065982065	CLEARCUT HP² INTREPID Micro-Coaxial system Dual Bevel 2.0 mm Slit Knife
			8065982265	CLEARCUT HP² INTREPID Micro-Coaxial system Dual Bevel 2.2 mm Slit Knife
			8065982465	CLEARCUT HP² INTREPID Micro-Coaxial system Dual Bevel 2.4 mm Slit Knife
		CLEARCUT HP²**	8065982665	CLEARCUT HP² Dual Bevel 2.6 mm Angled Slit Knife
			8065982865	CLEARCUT HP² Dual Bevel 2.8 mm Angled Slit Knife
			8065983065	CLEARCUT HP² Dual Bevel 3.0 mm Angled Slit Knife
			8065983265	CLEARCUT HP² Dual Bevel 3.2 mm Angled Slit Knife
		CLEARCUT HP*	8065992648	CLEARCUT HP Dual Bevel 2.6 mm Angled Slit Knife
			8065992848	CLEARCUT HP Dual Bevel 2.8 mm Angled Slit Knife
			8065993048	CLEARCUT HP Dual Bevel 3.0 mm Angled Slit Knife
			8065993248	CLEARCUT HP* Dual Bevel 3.2 mm Angled Slit Knife
		CLEARCUT	8065992647	CLEARCUT Dual Bevel 2.6 mm Angled Slit Knife
			8065992747	CLEARCUT Dual Bevel 2.75 mm Angled Slit Knife
			8065993047	CLEARCUT Dual Bevel 3.0 mm Angled Slit Knife
			8065993247	CLEARCUT Dual Bevel 3.2mm Angled Slit Knife

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Alcon Incisional Cutting Instruments by Type, Group and Sub-group				
Product Type	**Product Group**	**Product Sub-Group**	**Part Number**	**Description**
		CLEARCUT SATINSLIT	8065992645	CLEARCUT 2.6 mm Angled SATINSLIT Knife
			8065992745	CLEARCUT 2.75 mm Angled SATINSLIT Knife
			8065993045	CLEARCUT 3.0 mm Angled SATINSLIT Knife
			8065993245	CLEARCUT 3.2 mm Angled SATINSLIT Knife
Crescent Knives	A-OK^	A-OK^ SATIN CRESCENT	8065990001	SATINCRESCENT 2.3 mm Straight Bevel Up Crescent Knife
			8065990002	SATINCRESCENT 2.3 mm Angled Bevel Up Crescent Knife
	CLEARCUT	CLEARCUT HP* Crescent	8065997048	CLEARCUT HP 2.3 mm Dual Bevel Angled Crescent Knife
	A-OK	A-OK SATINSHORTCUT	80655993216	SATINSHORTCUT 3.2 mm Angled SHORTCUT Implant Knife
			80655993561	SATINSHORTCUT 3.5 mm Angled SHORTCUT Implant Knife
			8065994061	SATINSHORTCUT 4.1 mm Angled SHORTCUT Implant Knife
			8065995661	SATINSHORTCUT 5.2 mm Angled SHORTCUT Implant Knife
			8065993240	CLEARCUT Dual Bevel 1.0 mm Angled
	CLEARCUT	CLEARCUT Dual Bevel	8065993540	CLEARCUT Dual Bevel 3.5 mm Angled Implant Knife
			8065993740 (Obsoleted July 2022)	CLEARCUT Dual Bevel 3.75 mm Angled Implant Knife
			8065994140 (Obsoleted June 2023)	CLEARCUT Dual Bevel 4.1 mm Angled Implant Knife
			8065995240	CLEARCUT Dual Bevel 5.2 mm Angled Implant Knife
			8065995540 (Obsoleted June 2023)	CLEARCUT Dual Bevel 5.5 mm Angled Implant Knife
			8065996040 (Obsoleted December 2021)	CLEARCUT Dual Bevel 6.0 mm Angled Implant Knife
Standard Angle Knives	A-OK	A-OK Full Handle	8065921501	15° Ophthalmic Knife
			8065922201	22.5° Ophthalmic Knife
			8065923001	30° Ophthalmic Knife
			8065924501	45° Ophthalmic Knife
	I-KNIFE	I-KNIFE Ophthalmic Knives	8065401501	I-KNIFE 15° , 5.0 mm
			8065921517	I-KNIFE 15°, 0.75 mm MACKOOL Sideport
	I-KNIFE II Tips and Blades	I-KNIFE II Tips and Blades	8065921552	I-KNIFE II 15° Standard 5 mm
			8065921532	I-KNIFE II 15° Standard 3 mm
			8065921502	I-KNIFE II Standard 15°
			8065922202	22.5° Ophthalmic Knife
			8065923002	30° Ophthalmic Knife
Disc	A-OK	A-OK Disc	8065968161	2.25 mm Wide, Angled, Extended

Alcon Incisional Cutting Instruments by Type, Group and Sub-group				
Product Type	**Product Group**	**Product Sub-Group**	**Part Number**	**Description**
Knives		Knives		Bend Disc Knife
			8065968162	I Knife Angled Disc Knife
V-Lance Knives	A-OK	A-OK Corneal/Scleral V-LANCE$ Knives (MVR Blades)	8065911901	19 Gauge MVR+ Blade
			8065912001	20 Gauge MVR+ Blade
			8065912301	23 Gauge MVR+ Blade
			8065912501	25 Gauge MVR+ Blade
Sideport Knives	CLEARCUT	CLEARCUT Sideport	8065921540	CLEARCUT Dual Bevel 1.0 mm Angled Sideport Knife
			8065921541	CLEARCUT Dual Bevel 1.2 mm Angled Sideport Knife
			8065921542	CLEARCUT Dual Bevel 1.5 mm Angled Sideport Knife
Blades	Alcon Surgical Blades (ASB)	ASB Surgical Blades	8065005701	Hockey Stick Blade, Sharp All Around
			8065006401	¾" Edge, Round, Sharp Tip (Surgical Blade 64)
			8065006601	Surgical Blade 66
			8065006701	Surgical Blade 67
			8065006901	2.3 mm Tunnel Blade (Straight) (Surgical Blade 69)

^A-OK– Alcon Ophthalmic Knives; *#I-KNIFE – "I" refers to "eye"*; *** HP -2 High Performance design for wound enlargement;*
** HP – High Performance* design to eliminate unintended incision enlargement; *$V-Lance-Vitrectomy Lance;*
+MVR Knife – Micro-vitreoretinal

Alcon Incisional Safety Knives by Type, Group and Sub-group				
Product Type	**Product Group**	**Product Sub-group**	**Part Number**	**Description**
Slit Knives	CLEARCUT Slit Safety	CLEARCUT Safety INTREPID Micro-coaxial System (Single Bevel)	8065772245	2.2 mm CLEARCUT Safety INTREPID Single Bevel
			8065772445	2.4 mm CLEARCUT Safety INTREPID Single Bevel
		CLEARCUT Safety INTREPID Micro-	8065772265	2.2 mm CLEARCUT Safety INTREPID Dual Bevel
			8065772465	2.4 mm CLEARCUT Safety INTREPID Dual Bevel
		CLEARCUT Safety SATINSLIT	8065772645	2.6 mm CLEARCUT Safety Slit Single Bevel
			8065772745	2.75 mm CLEARCUT Safety Slit Single Bevel
Crescent Knives	CLEARCUT Crescent Safety	CLEARCUT Safety	8065770002	2.3 mm CLEARCUT Safety Crescent
Sideport Knives	CLEARCUT Sideport Safety	CLEARCUT Safety Sideport	8065771540	1.0 mm CLEARCUT Safety Sideport
			8065771541	1.2 mm CLEARCUT Safety Sideport

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		CLEARCUT Safety Sideport	8065771501	15º CLEARCUT Safety SAB Sideport	2
			8065773001	30º CLEARCUT Safety SAB Sideport	

4.2 Harmonized Standards and Common Specifications

Alcon acknowledges that the General Safety and Performance Requirements are fulfilled through compliance with quality system requirements, standards, regulations, and guidance documents.

Non-product specific guidance and other regulatory documents (e.g. MEDDEV, WHO guideline) are acknowledged as part of the General Safety and Performance Requirements and are referenced in relevant Standard Operating Procedures (SOP) within Alcon's Quality Management System.

As such, Alcon's Quality Management System is maintained and audited for compliance with ISO / EN ISO 13485.

Product specific standards are identified below in the List of Applicable Standards.

Alcon ensures product compliance via the Reference Standards Management Process

Document Number	Title
ASTM D4169:2016	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F899:2019	Standard Specification for Wrought Stainless Steels for Surgical Instruments
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN 556-1:2001/COR:2006	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
EN 62366-1:2015/A1:2020	Medical devices – Part 1: Application of Usability Engineering to Medical Devices
EN ISO 10993-1:2009/COR:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008/COR:2009	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals – Technical Corrigendum 1
EN ISO 10993-10:2013/COR:2013	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity Considered but

Document Number	Title
	determined to be not relevant in Section 6.1.2.1
EN ISO 10993-12:2012	Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials
EN ISO 10993-18:2009	Biological Evaluation of Medical Devices – Part 18: Chemical characterization of materials within a Risk Management Process
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
EN ISO 11137-1:2015/A2:2019	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016/COR:2018	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14155:2011/COR:2011	Clinical investigation of medical devices for human subjects -- Good clinical practice
ISO 14644-1:2015	Cleanrooms and associated controlled environments - part 1: classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments - part 2: monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information

Document Number	Title
	to be supplied – Part 1: General requirements
EN ISO 22442-1:2015	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
EN ISO 22442-2:2015	Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling
EN ISO 22442-3:2007	Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
EN ISO 80369-7:2017 COR 2017	Small-bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular Or Hypodermic Applications
ISO 3166-1:2013	Codes for the representation of names of countries and their subdivisions – Part I: Country Codes
ISO 639-1:2002 (R2019)	Codes for the Representation of Names of Languages - Part 1: Alpha-2 Code
ISO/TR 15499:2016	Biological evaluation of medical devices – Guidance on the conduct of biological evaluation within a risk management process
ISO 14698-1:2003 (R2014)	Cleanrooms and associated controlled environments - biocontamination control - part 1: general principles and methods
ISTA 2A:2011	Packaged-products 150 Lb (68 Kg) Or Less