Thay mặt VPDD Alcon Pharmaceuticals Ltd tại Hà Nội
VĂN PHÒNG ĐẠI DIỆN TẠI T.P HÀ NỘI
Bùi Thị Thu Thủy
Trưởng Đại Diện

VĂN PHÒNG ĐẠI DIỆN ALCON PHARMACEUTICALS LTD TẠI HÀ NỘI
C=VN, S=THÀNH PHỐ HÀ NỘI, CN=VĂN PHÒNG ĐẠI DIỆN ALCON PHARMACEUTICALS LTD TẠI HÀ NỘI, OID.0.9.2342.19200300.100.1.1=MST:0106885105
your signing location here
2022.01.10 16:43:55+07'00'

Alcon

Alcon Cutting Instruments, FW-SG-014

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 and Version: FW-SG-016, Revision 6
Device Trade Name: Alcon Cutting Instruments
Supersedes (Date): 26-Apr-2019

Manufacturer: Alcon Laboratories, Incorporated
Address: 6201 South Freeway, Fort Worth, TX 76134-2099, USA

Manufacturing Sites:
Alcon Research, LLC
714 Columbia Ave, Sinking Spring, PA 19608
USA

Authorized Representative* in the European Community:
Alcon Laboratories Belgium

Address: Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

* Previously Alcon Laboratories (UK) Ltd., Frimley Business Park, Frimley, Camberley, GU16 7SR, Surrey, United Kingdom

Device (Trade Name)	GMDN Code & Term	Class
Alcon Cutting Instruments – See Attachment	46741 Ophthalmic Knife, single-use	Class IIa

Alcon Cutting Instruments, FW-SG-014

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 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 0345

Notified Body: TÜV SÜD Product Service GmbH

Identification number: 0123

Address: Ridlerstraße 65 D-80339 München, Germany

Regulations, Directives and Standards Applied: EN ISO 13485 as currently published

Place of Issue:	Date of Issue:	
Alcon Laboratories, Incorporated, Fort Worth, TX USA	15-Jan-2020	Tezel Amy Digitally signed by Tezel Amy DN: dc=com, dc=novartis, ou=people, ou=AL, serialNumber=1781702, cn=Tezel Amy Date: 2020.01.15 08:53:19 -06'00' Name/Title/Function/Date: Amy Tezel, Vice President, Global Regulatory Affairs

Product List

Part Number	Description	Date Added	Last Date of Manufacture	Drawing Number
A-OK Ophthalmic Knives - Full Handle				
8065921501	15° Ophthalmic Knife	Feb. 5, 1996		IA-701
8065922201	22.5° Ophthalmic Knife	Feb. 5, 1996		IA-701
8065923001	30° Ophthalmic Knife	Feb. 5, 1996		IA-701
8065924501	45° Ophthalmic Knife	Feb. 5, 1996		IA-701
A-OK V-Lance				
8065911901	19 Gauge [1.6mm] V-Lance™ Knife	Feb. 5, 1996		IA-706
8065912001	20 Gauge [1.3mm] V-Lance™ Knife	Feb. 5, 1996		IA-706
8065912301	23 Gauge Cannula Compatible MVR Knife	Sept. 2007		IA-821
8065912501	25 Gauge MVR Knife	Aug. 2006		IA-821
A-OK Disc Knives - Full Handle				
8065968161	Angled Disc Knife	Feb. 5, 1996		IA-743
A-OK Satin Crescent Knives - Full Handle				
8065990001	SatinCrescent™ Straight Crescent Knife	Feb. 5, 1996		IA-713
8065990002	SatinCrescent™ Angled Bevel Up Knife	Feb. 5, 1996		IA-714

FW-SG-014, Declaration of Conformity Alcon Cutting Instruments Product List

Part Number	Description	Date Added	Last Date of Manufacture	Drawing Number
A-OK Satin Slit Knives - Full Handle				
8065992561	SatinSlit™ 2.5mm Angled Slit Knife	Apr. 18, 1997		IA-708
8065992645	CLEARCUT™ 2.6mm Angled SatinSlit™ Knife	Sept. 2007		IA-813
8065992745	CLEARCUT™ 2.75mm Angled SatinSlit™ Knife	Oct. 20, 1998		IA-813
8065992761	SatinSlit™ 2.75mm Angled Slit Knife	Feb. 5, 1996		IA-708
8065992961	SatinSlit™ 3.0mm Angled Slit Knife	Feb. 5, 1996		IA-708
8065993045	CLEARCUT™ 3.0mm Angled SatinSlit™ Knife	Oct. 20, 1998		IA-813
8065993201	SatinSlit™ 3.2mm Straight Slit Knife	Feb. 5, 1996		IA-709
8065993245	CLEARCUT™ 3.2mm Angled Slit Knife	Nov. 14, 1997		IA-813
8065993261	SatinSlit™ 3.2mm Angled Slit Knife	Feb. 5, 1996		IA-708
8065993445	SatinSlit™ 3.4mm Angled Slit Knife	Sept. 2, 1999		IA-813
A-OK Satin ShortCut Slit Knives - Full Handle				
8065993561	SatinShortCut™ 3.5mm Angled ShortCut® Implant Knife	Feb. 5, 1996		IA-750
8065994061	SatinShortCut™ 4.1mm Angled ShortCut® Implant Knife	Feb. 5, 1996		IA-750
8065995661	SatinShortCut™ 5.2mm Angled ShortCut® Implant Knife	Feb. 5, 1996		IA-750
I-Knife Ophthalmic Knives - Full Handle				
8065401501	I-KNIFE™ 15° Cutting Instrument	Feb. 5, 1996		IA-730
I-Knife Disc Knives - Full Handle				
8065968162	I-KNIFE™ *Angled Disc Knife*	Feb. 5, 1996		IA-743
I-Knife II Ophthalmic Knives - Blade & Tip				

FW-SG-014, Declaration of Conformity Alcon Cutting Instruments Product List

Part Number	Description	Date Added	Last Date of Manufacture	Drawing Number
8065921532	I-KNIFE™ II 3mm Cutting Instrument	Feb. 5, 1996		IA-704
8065921552	I-KNIFE™ II 5mm Cutting Instrument	Feb. 5, 1996		IA-705
I-Knife II Satin Slit Knives - Blade & Tip				
8065992762	I-KNIFE™ II 2.75mm Angled SatinSlit™ Slit Knife	Feb. 5, 1996		IA-747
8065992962	I-KNIFE™ II 3.0mm Angled SatinSlit™ Slit Knife	Feb. 5, 1996		IA-747
8065993262	I-KNIFE™ II 3.2mm Angled SatinSlit™ Slit Knife	Feb. 5, 1996		IA-747
Threaded Tip Cutting Instruments - Blade & Tip				
8065921502	15° Ophthalmic Knife	Feb. 5, 1996		IA-703
8065922202	22.5° Ophthalmic Knife	Feb. 5, 1996		IA-703
8065923002	30° Ophthalmic Knife	Feb. 5, 1996		IA-703

FW-SG-014, Declaration of Conformity Alcon Cutting Instruments Product List

Part Number	Description	Date Added	Last Date of Manufacture	Drawing Number
I-Knife (MacKool Sideport Knife)				
8065921517	I-KNIFE™ Mackool Sideport Knife	Aug. 6, 1997		IA-812
Alcon Surgical Blades				
8065005701	Surgical Blade 57	Feb. 5, 1996		25-0010
8065006401	Surgical Blade 64	Feb. 5, 1996		25-0011
8065006601	Surgical Blade 66	Feb. 5, 1996		25-0013
8065006701	Surgical Blade 67	Feb. 5, 1996		25-0014
8065006901	Surgical Blade 69	Feb. 5, 1996		25-0015
ClearCut™ Dual Bevel Knives				
8065921540	CLEARCUT™ Dual Bevel 1.0mm Angled Sideport Knife	Oct. 12, 2000		IA-824
8065921541	CLEARCUT™ Dual Bevel 1.2mm Angled Sideport Knife	July 1, 2003		IA-824
8065921542	CLEARCUT™ Dual Bevel 1.5mm Angled Sideport Knife	July 1, 2003		IA-824
8065993240	CLEARCUT™ Dual Bevel 3.2mm Angled Sideport Knife	Oct. 12, 2000		IA-823
8065993540	CLEARCUT™ Dual Bevel 3.5mm Angled Sideport Knife	Oct. 12, 2000		IA-823
8065993740	CLEARCUT™ Dual Bevel 3.75mm Angled Sideport Knife	Oct. 12, 2000		IA-823
8065994140	CLEARCUT™ Dual Bevel 4.1mm Angled Sideport Knife	Oct. 12, 2000		IA-823
8065995240	CLEARCUT™ Dual Bevel 5.2mm Angled Sideport Knife	Oct. 12, 2000		IA-823
8065995540	CLEARCUT™ Dual Bevel 5.5mm Angled Implant Knife	Oct. 12, 2000		IA-823
8065996040	CLEARCUT™ Dual Bevel 6.0mm Angled Implant Knife	Oct. 12, 2000		IA-823
8065992647	CLEARCUT™ Dual Bevel 2.6mm Angled Slit Knife	Oct. 12, 2000		IA-817

2

FW-SG-014, Declaration of Conformity Alcon Cutting Instruments Product List

Part Number	Description	Date Added	Last Date of Manufacture	Drawing Number
8065992747	CLEARCUT™ Dual Bevel 2.75mm Angled Slit Knife	Oct. 12, 2000		IA-817
8065993047	CLEARCUT™ Dual Bevel 3.0mm Angled Slit Knife	Oct. 12, 2000		IA-817
8065993247	CLEARCUT™ Dual Bevel 3.2mm Angled Slit Knife	Oct. 12, 2000		IA-817
ClearCut™ Single Bevel Slit Knives				
8065991845	CLEARCUT™ INTREPID® micro-coaxial system Single Bevel 1.8 Slit Knife	May 2007		IA-822
8065992045	CLEARCUT™ INTREPID® micro-coaxial system Single Bevel 2.0 Slit Knife	May 2007		IA-822
8065992245	CLEARCUT™ INTREPID® micro-coaxial system Single Bevel 2.2 Slit Knife	May 2007		IA-822
8065992445	CLEARCUT™ INTREPID® micro-coaxial system Single Bevel 2.4 Slit Knife	May 2007		IA-822
ClearCut™ *HP* Dual Bevel Knives				
8065992648	CLEARCUT™ *HP* Dual Bevel 2.6mm Angled Slit Knife	July 1, 2003		IA-819
8065992848	CLEARCUT™ *HP* Dual Bevel 2.8mm Angled Slit Knife	July 1, 2003		IA-819
8065993048	CLEARCUT™ *HP* Dual Bevel 3.0mm Angled Slit Knife	July 1, 2003		IA-819
8065993248	CLEARCUT™ *HP* Dual Bevel 3.2mm Angled Slit Knife	July 1, 2003		IA-819
8065997048	CLEARCUT™ *HP* Dual Bevel Angled Crescent Knife	Mar. 21, 2005		IA-820
ClearCut™ *HP²* Dual Bevel Slit Knives				
8065981865	CLEARCUT™ *HP²* INTREPID® micro-coaxial system Dual Bevel 1.8 Slit Knife	December 2006		IA-825
8065982065	CLEARCUT™ *HP²* INTREPID® micro-coaxial system Dual Bevel 2.0 Slit Knife	December 2006		IA-825
8065982265	CLEARCUT™ *HP²* INTREPID® micro-coaxial system Dual Bevel 2.2 Slit Knife	January 2006		IA-825

FW-SG-014, Declaration of Conformity Alcon Cutting Instruments Product List

Part Number	Description	Date Added	Last Date of Manufacture	Drawing Number
8065982465	CLEARCUT™ *HP²* INTREPID® micro-coaxial system Dual Bevel 2.4 Slit Knife	January 2006		IA-825
8065982665	CLEARCUT™ *HP²* Dual Bevel 2.6mm Angled Slit Knife	Mar. 21, 2005		IA-825
8065982865	CLEARCUT™ *HP²* Dual Bevel 2.8mm Angled Slit Knife	Mar. 21, 2005		IA-825
8065983065	CLEARCUT™ *HP²* Dual Bevel 3.0mm Angled Slit Knife	Mar. 21, 2005		IA-825
8065983265	CLEARCUT™ *HP²* Dual Bevel 3.2mm Angled Slit Knife	Mar. 21, 2005		IA-825

8.2 Reference Documents

ALCON® Cutting Instruments

Reference Documents

Alcon® ensures product compliance via the Reference Standards Management process.

Document Number	Title
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F899	Standard Specification for Wrought Stainless Steels for Surgical Instruments
EN 980	Symbols for use in the labelling of medical devices
EN 1041	Information supplied by the manufacturer of medical devices
EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
EN 20594-1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process – Technical Corrigendum 1
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 11137-1	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	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products TECHNICAL CORRIGENDUM 1
EN ISO 11737-2	Sterilization of medical devices – Microbiological methods –

Document Number	Title
	Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes – Technical Corrigendum 1
EN ISO 14971	Medical devices – Application of risk management to medical devices
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 22442-1,2,3	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management, Part 2: Controls on sourcing, collection and handling, Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
MEDDEV 2.7.1	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
MEDDEV 2.5/5	TRANSLATION PROCEDURE
MEDDEV 2.11/1	APPLICATION OF COUNCIL DIRECTIVE 93/42/EEC TAKING INTO ACCOUNT THE COMMISSION DIRECTIVE 2003/32/EC FOR MEDICAL DEVICES UTILISING TISSUES OR DERIVATIVES ORIGINATINF FROM ANIMALS FOR WHICH A TSE RISK IS SUSPECTED A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES