

REVISION HISTORY		
REV	CN	DATE
E	CN048518ECN	9/26/13
F	CN068283ECN	7/11/16
G	CN069432ECN	10/17/16
H	CN069946ECN	10/26/16
J	CN098951ECN	21-JUL-2020

DECLARATION OF CONFORMITY

EU MEDICAL DEVICE DIRECTIVE

FOR

LIO (LASER INDIRECT OPHTHALMOSCOPE)

PUREPOINT ACCESSORIES



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By	Date
SHAKU NITTURKAR	1/31/08

Title	Drawing Number	Revision
DOC,MDD,LIO PUREPOINT ACCESSORIES	931-4130-001	J

DECLARATION OF CONFORMITY

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

Annex II (3) ☒Annex III ☐Annex V ☐Annex VII ☐Annex II (4) ☐Annex IV ☐Annex VI ☐

Declaration of Conformity Version No.: J

Supersedes (Date): 24-Oct-2016

Manufacturer: Alcon Laboratories, Inc.

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

Manufacturing Site(s):
Alcon Research, LLC
15800 Alton Parkway
Irvine, CA 92618, USAAuthorized Representative* in the European Community:
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United Kingdom

Medical Device (Trade Name)	GMDN Code	Catalogue Number	Class
ASSY, SHIP, LIO PUREPOINT®	32729	8065751050	IIb
SHIP ASSY, PUREPOINT® LIO	32729	8065752987	IIb

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, Inc. 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, 80339 Munich, Germany.

Place of Issue: Lake Forest, CA, USA	Date of Issue: 27-JUL-2020	Title/Function: Global Regulatory Affairs
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Title

DOC,MDD,LIO PUREPOINT ACCESSORIES

Drawing Number

931-4130-001

Revision

J