

REVISION HISTORY		
REV	CN	DATE
P0	NOT REL	20-JUL-2020
A	CN098951ECN	21-JUL-2020

DECLARATION OF CONFORMITY

EU MEDICAL DEVICE DIRECTIVE

FOR

PUREPOINT® LASER



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By	Date
JACQUELINE CEPEDA	20-JUL-2020

Title	Drawing Number	Revision
DOC,PUREPOINT LASER	931-4120-451	A

DECLARATION OF CONFORMITY			
(check all conformity route(s) based on EU MDD Article 11 requirements for the device class and specifics)			
Annex II (3) <input checked="" type="checkbox"/>	Annex III <input type="checkbox"/>	Annex V <input type="checkbox"/>	Annex VII <input type="checkbox"/>
Annex II (4) <input type="checkbox"/>	Annex IV <input type="checkbox"/>	Annex VI <input type="checkbox"/>	
Declaration of Conformity Version No.: A			
Supersedes (Date): N/A			
Manufacturer: Alcon Laboratories, Inc.		Authorized Representative* in the European Community:	
Address: 6201 South Freeway, Fort Worth, TX 76134-2099, USA		Alcon Laboratories Belgium	
Manufacturing Site(s): Alcon Research, LLC 15800 Alton Parkway Irvine, CA 92618, USA		Address: Lichterveld 3, 2870 Puurs-Sint-Amands, Belgium	
		*Previously Alcon Laboratories (U.K.) Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom	
Medical Device (Trade Name)	GMDN Code	Catalogue Number	Class
PurePoint® Laser System	36150	8065750597	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 <input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/>			
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:	Date of Issue:		
Lake Forest, CA, USA	27-JUL-2020	Title/Function: Global Regulatory Affairs	