

REVISION HISTORY		
REV	CN	DATE
C	20100332	3/8/10
D	CN029371ECN	4/5/12
E	CN048518ECN	9/26/13
F	CN064602ECN	11/17/15
G	CN098951ECN	21-JUL-2020

DECLARATION OF CONFORMITY

EU MEDICAL DEVICE DIRECTIVE

FOR

ADAPTATIONS

(LASER ACCESSORIES)



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By	Date
LASZLO ROMODA	6/24/08

Title	Drawing Number	Revision
DOC,MDD,LASER ACCESSORIES,ADAPT	931-4140-002	G

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 type="checkbox"/>	Annex III <input type="checkbox"/>	Annex V <input type="checkbox"/>	Annex VII <input checked="" type="checkbox"/>
Annex II (4) <input type="checkbox"/>	Annex IV <input type="checkbox"/>	Annex VI <input type="checkbox"/>	
<p>Declaration of Conformity Version No.: G</p> <p>Supersedes (Date): 03-Nov-2015</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Manufacturer: Alcon Laboratories, Inc.</p> <p>Address: 6201 South Freeway, Fort Worth, TX 76134-2099, USA</p> <p>Manufacturing Site(s): Alcon Research, LLC 15800 Alton Parkway Irvine, CA 92618, USA</p> </div> <div style="width: 45%;"> <p>Authorized Representative* in the European Community: Alcon Laboratories Belgium</p> <p>Address: Lichterveld 3, 2870 Puurs-Sint-Amands, Belgium</p> <p>*Previously: Alcon Laboratories (U.K.) Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom</p> </div> </div>			
Medical Device (Trade Name)	GMDN Code	Catalogue Number	Class
ASSY, SHIP, ADV ADAPTATION	36184	8065751195	I (non-sterile)
ASSY,SHIP,ADV ADAPT W/DUAL SLT	36184	8065751193	I (non-sterile)
ADAPTOR, HAAG-STREIT 900 BM/TOPCON SLE 3	36184	8065-5011-01	I (non-sterile)
<p>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.</p> <p>Alcon Laboratories, Inc. hereby declares under its sole responsibility that the listed device(s) and Quality Systems conform(s) to:</p> <p style="text-align: center;">EU MDD 93/42/EEC as amended</p> <p>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.</p> <p>Notified Body Information: Applicable <input type="checkbox"/> Not Applicable <input checked="" type="checkbox"/></p> <p>Conformity Assessment Certificate Number(s): NA</p> <p>Notified Body: N/A Identification number: N/A</p> <p>Address: N/A</p>			
<p>Place of Issue:</p> <p>Lake Forest, CA, USA</p>	<p>Date of Issue:</p> <p>27-JUL-2020</p>	<p>Title/Function: Global Regulatory Affairs</p>	

Title	Drawing Number	Revision
DOC,MDD,LASER ACCESSORIES,ADAPT	931-4140-002	G