

## DECLARATION OF CONFORMITY

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

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

Technical Documentation Identification: DU-VC-005

Declaration of Conformity Version No.: 03

Supersedes (Date): 12/20/2018

Manufacturer: Alcon Laboratories, Inc.

Authorized Representative in the European Community: Alcon Laboratories (UK) Ltd.

Address: 6201 South Freeway Fort Worth, TX 76134 USA

Address: *Frimley Business Park Frimley, Camberley Surrey, GU16 7SR, United Kingdom*

Manufacturing Site(s):

*CIBA VISION GmbH**CIBA VISION Asian Manufacturing and Logistics Pte Ltd.**Alcon Laboratories, Inc.*

Device (Trade Name)	GMDN Code and Term	Catalogue Number	Class
Focus DAILIES (refikon A) soft contact lenses	47B41 Soft corrective contact lens, daily-disposable	NA	Ila
Focus Dailies Toric			
Focus Dailies Progressives			

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): 597047

Notified Body: BSI

Identification number:0086

Address: Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP UK

Regulations, Directives and Standards Applied: EN ISO 13485:2012

Place of Issue:  
Alcon Laboratories,  
Inc. Fort Worth, TX  
USA

Date of Issue: **02-12-19**

Lakota  
Signature: **Sherri**  
Name: **Sherri Lakota**  
Title/Function: **Sr. Director GRA VC**

Agile - Issued by Lakota Sherri  
Name: Sherri Lakota  
Signature: Sherri Lakota  
Title/Function: Sr. Director  
Date: 2019/02/12 07:41:38 -0600

Date: \_\_\_\_\_