

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 II Annex VII Annex II (3) Annex VI Annex IV

Technical Documentation Identification: DU-VC-005

Declaration of Conformity Version No.: D3

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 Terms	Catalogue Number	Class
Focus DAILIES (refilcon 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
Model - Agile - Issued by
Sample - Issued by
Issued by Lakota Sherri
Date: 2019/02/12 07:41:38 -0500

Date: _____