

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.: 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 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: _____