

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 07:41:36 -0500

Date: _____