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1400 North Goodman Street
Rochester, NY 14609 USA
585.338.6000

EU Declaration of Conformity

In accordance with Annex IV of Regulation (EU) 2017/745 of the European Parliament and of the Council

Technical Documentation Number	745.002
Legal Manufacturer	Bausch & Lomb Incorporated 1400 North Goodman St. Rochester, NY 14609 USA SRN: US-MF-000001029
European Authorized Representative	Bausch & Lomb Incorporated Cork Road Industrial Estate Waterford, X91 V383, Ireland SRN: IE-AR-000000094
Notified Body	National Standards Authority of Ireland (NSAI) 1 Swift Square Northwood, Santry Dublin 9, Ireland Notified Body Number: 0050
Products	Bausch + Lomb ULTRA® ONE DAY (kalifilcon A) Contact Lenses
Product Code(s)	KAPBSDD
Basic UDI-DI	0310119B0020YV
Global Medical Devices Nomenclature Code-Term Name	47841 – Soft corrective contact lens, daily-disposable
EMDN Code	Q021004010101
Classification	Class IIa (Annex VIII, Rule 5)
Conformity Assessment Procedure	Regulation (EU) 2017/745 Annex IX Conformity assessment based on a quality management system and on assessment of technical documentation
Intended Purpose	Bausch + Lomb kalifilcon A Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.

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This EU Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.

We, Bausch & Lomb Incorporated, hereby declare the above listed Medical Devices comply with Medical Device Regulation (EU) 2017/745. Above products are developed and manufactured in compliance with the EU MDR and the applicable European harmonized standards and Common Specifications as applicable.

This declaration is made on the basis of EU Quality System Certificate Number MD19.1854 and EU MDR EC Certificate Number 745.002, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745 and the products above comply with Annex I.

Place of Issue: Refer to Legal Manufacturer's Address above.

Signature: _____ Date: Sept 20, 2021

Name/Title/Position: Barbara Klube-Falso, Director, Regulatory Affairs