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1400 North Goodman Street
Rochester, NY 14609 USA
645.330.8000

EU Declaration of Conformity

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

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| 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 V983, 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 (kalliflcon A) Contact Lenses |
| Product Code(s) | KAPBSDD |
| Basic UDI-DI | 031011980020YV |
| 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 kalliflcon 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. |

BAUSCH+LOMB

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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: Barbara Klube-Falao Date: Sept 30 2021

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

FOR EU MDR RELATED IMPORTER AND DISTRIBUTOR COMPLIANCE VERIFICATION ACTIVITIES ONLY.