BAUSCH + LOMB

STATEMENT

about transitional period referred to in Art. 120 of

EU Regulation 2017/745

To whom it may concern,

We, Bausch + Lomb, the Legal Manufacturer of products listed in Annex 1 to this statement confirm that:

All these medical devices are covered by valid certificates, which confirm meeting of applicable requirements given in Medical Devices Directive 93/42/EEC and

All these medical devices are covered by transitional period referred to in Art. 120 section 2 and 3 of EU Regulation No. 2017/745 of 5 April 2017, revised by EU Regulation 2023/607 of 15 March 2023.

With this statement we confirm also:

All certificates issued in accordance with Directive 93/42/EEC were still valid on 26th of May 2021 containing in their scope products from Annex 1, have not been withdrawn and are valid until 26th of May 2024,

- All products continue to comply with Directive 93/42/EEC,
- There are no significant changes in their design and intended purposes,
- The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health,

As the Legal Manufacturer of medical devices, we have implemented and maintain valid quality management system with the scope applicable for manufactured medical devices,

As the Legal Manufacturer we are in contact with the Notified Body to sign a written agreement until 26th September 2024 to conduct conformity assessments of these products in accordance with Medical Devices Regulation (UE) 2017/745.

Name: Casey Costello

Title: Director Quality Systems

Bausch + Lomb, Rochester

Date: 23 February 2024

Signature: 

BAUSCH + LOMB

Annex 1

Statement about transitional period referred to in Art. 120 of EU Regulation 2017/745

- Viscoelastics, HPMC (Hydroxypropylmethylcellulose)
- Viscoelastics, bacteria fermented
- IOL, Anterior Chamber PMMA Lenses
- IOL, Posterior Chamber PMMA Lenses
- IOL, Posterior Chamber Lenses, Foldable, Softport and Softflex, and Hydrophilic Acrylic
- IOL, Posterior Chamber Lenses, Foldable, enVista
- IOL, Posterior Chamber Lenses, Foldable, Hydrophobic Acrylic
- Silicone Oil
- Ophthalmic Microsurgical System, Stellaris
- Ophthalmic Microsurgical System, Stellaris PC
- Ophthalmic Microsurgical Handpieces, for Premiere
- Ophthalmic Microsurgical Handpieces, for Millineum
- Ophthalmic Microsurgical Handpieces, for Stellaris PC
- Ophthalmic Microsurgical Handpieces, for Stellaris
- Ophthalmic Procedure Packs, with energy driven components for Protege, Premiere, Millennium
- Ophthalmic Procedure Packs, with energy driven components for Stellaris
- Ophthalmic Procedure Packs, with energy driven components for Stellaris PC
- Non-active Ophthalmic Procedure Packs, for Protege, Premiere, Millennium
- Non-active Ophthalmic Procedure Packs, for Stellaris
- Non-active Ophthalmic Procedure Packs, for Stellaris PC
- Non-active Ophthalmologic Product, Balanced Salt Solution
- Non-active Ophthalmologic Product, sterile Cannula and Cystotomes
- Non-active Ophthalmologic Product, Laseredge knife
- Non-active Ophthalmologic Product, non-sterile Cystotomes
- Non-active Ophthalmologic Product, Infusion/Non-sterile Cannula
- Non-active Ophthalmologic Product, Lens Insertion Device, disposable - use with Silicone IOLs
- Non-active Ophthalmologic Product, Lens Insertion Device, disposable - use with Acrylic IOLs
- Non-active Ophthalmologic Product Lens Insertion Device, cartridge with disposable handpiece
- Non-active Ophthalmologic Product, Lens Insertion Device, cartridge with reusable handpiece
- Non-active Ophthalmologic Product, Independent Viewing Chamber
- Non-active Ophthalmologic Product, Phaco Needle
- Active Ophthalmic Device, Irregation/Aspiration handpiece
- Active Ophthalmic Device, Bipolar Forceps
- Perfluorocarbons, DK-Line, Okta-line