



Health Technology Certification

# EC-CERTIFICATE

## FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

### **Appasamy Associates Private Limited**

S.F.No. 144/1, Navammal Kapper Village, M.N.Kuppam,  
Thennal Post, Kandamangalam Taluk, Villupuram District,  
Tamil Nadu 605102 India

for design and manufacture of

### **Manufacturing of Ophthalmic Intraocular Surgical Blades & Ophthalmic Micro Surgical Instruments**

*Further details are given overleaf*

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

**Certificate No:** 2456C04210501  
**Issue Date:** 07/05/2021  
**Original Approval:** 07/05/2021  
**Valid until:** 26/05/2024  
**References:** W001 2456 01

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director

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## Attachment to Certificate

No: 2456C04210501

Issued: 07/05/2021

### Products included:

#### Ophthalmic Intraocular Surgical Blades

- Appa Blade
- Appa Glide
- Appa Blade - Navigator
- Appa Blade - Samurai Edge

#### Ophthalmic Micro Surgical Instruments

- Surgical Knives
- Cannula
- Scissors
- Forceps
- Hooks, Spatulas, Manipulators
- Corneoscleral Punches
- Needles
- Retractors
- Lacrimal Probe
- Lacrimal Dilators
- Surgical Procedure Kits
- Calipers
- Needle Holder
- Speculum
- Markers

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

A blue ink signature of George Pappous, written in a cursive style.

**FILIPPOS KOTTIS**  
Certification Director

A blue ink signature of Filippou Kottis, written in a cursive style.

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