

Certificate of Compliance



We hereby declare that the technical files of all the items in each product group complies with the requirements of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC Class.

Certificate No.: CE-16200

Manufacturer

Name : ASTRA BIOSCIENCE LIMITED
Address : PLOT NO, 4 & SDF III/UNIT 5, KINFRA INDUSTRIAL PARK, KORATTY THRISSUR, KERALA- 680309
EC REP : MEDITA TRADING AB, SÄBYVÄGEN 5A, 573 39 TRANÅS, SWEDEN
(Details As per Annexure I and II)

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC class D.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of test report of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	26 th June 2021
1 st Surveillance Audit Due	25 th June 2022
2 nd Surveillance Audit Due	25 th June 2023
Certificate Expiry	25 th June 2024



Authorised Signatory





Certificate of Compliance

Appendix-I

Appendix to Certificate no.:- CE-16200

Manufacturer : ASTRA BIOSCIENCE LIMITED



This certificate referred to above covers the following products like:

Non Sterile IVD	
SI No	Product Name
1	“Easyrate” Disposable ESR Pipette
2	Test Tube Racks
3	Rack for ESR Pipettes
4	Disposable Test Tubes
5	Stoppers for Test Tubes
6	Pasteur Pipettes
7	Tips for Micro Pipettes
8	Sample/Urine Containers
9	Sample/Stool Containers With Spoon
10	Petri Plates
11	Embedding Cassettes
12	Embedding Spare “O” Ring
13	Micro Centrifuge tubes
14	Storage Vials
15	Centrifuge Tubes
16	Sample Cup for Analyzers
17	Cervical Brush
18	Cyto Brush
19	Cervical Spatula
20	Cotton Swabs / DACRON Swabs/ Polyester Swabs
21	Swab Stick in Hard PP Tube





Certification & Inspection



Certificate of Compliance

Appendix-II

Appendix to Certificate no.:- CE-16200

Manufacturer :

ASTRA BIOSCIENCE LIMITED



This certificate referred to above covers the following products like:

Sterile IVD	
SI No	Product Name
1	Sample/Urine Containers
2	Sample/Stool Containers With Spoon
3	Petri Plates
4	PAP Kits
5	PAP Smear Kits
6	Swab Stick in Hard PP Tube
7	Pasteur Pipettes
8	Centrifuge Tubes
9	Cervical Brush
10	Cyto Brush
11	Cervical spatula
12	Cotton Swabs / DACRON Swabs/ Polyester Swabs
13	Test Tubes
14	Tips for Micro Pipettes
15	Micro Centrifuge tubes
16	Storage Vials
17	Filter Tips
18	Cryo Vials
19	Self Standing Tubes
20	Disposable Test Tubes

