Certificate of Compliance

CE

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 I.

Certificate No.: CE-3174

Manufacturer

Name : **CML BIOTECH LIMITED**

Address

Manufacturing Site- 1 : **A1, A2, B1& B2, TOWER 1, INKEL INDUSTRIAL COMPLEX, ANGAMALY SOUTH -PO, ERNAKULAM DISTRICT, KERALA - 683 573, INDIA**

Manufacturing Site 2 : **PLOT NO: 2, INKID INDUSTRIAL AREA, INKEL BUSINESS PARK, ANGAMALY SOUTH - PO, ERNAKULAM DISTRICT, KERALA – 683573, INDIA**

Reg. Office : **4/434B, KARUKUTTY P.O, ANGAMALY, ERNAKULAM DISTRICT, KERALA, INDIA, PIN-683576**

Products : **ALCOHOL PREP PAD, ADHESIVE PLASTER, PLATELET-RICH PLASMA (PRP) TUBES, PLATELET-RICH PLASMA (PRP) KITS, BLOOD COLLECTION NEEDLES.**

EC REP : **MEDITA TRADING AB, SÄBYVÄGEN 5A, 573 39 TRANÅS, SWEDEN**

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 I.

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 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	31st May 2022
1st Surveillance Audit Due	30th May 2023
2nd Surveillance Audit Due	30th May 2024
Certificate Expiry (subject to the company maintaining its system to the required standard)	30th May 2025

Authorised Signatory

UK Certification & Inspection Ltd.