

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-3880

Manufacturer : PENTAVEST HOLDINGS SDN BHD

Address : NO. 9574-9578, JALAN PTB 2, KAWASAN PERINDUSTRIAN
TANGGA BATU, 76400 MELAKA

Products : NANO ANTIMICROBIAL NITRILE EXAMINATION GLOVES

EC REP : MEDITA TRADING AB, SÄBYVÄGEN 5A, 57339 TRANAS,
SWEDEN. EUDAMED SRN NO:-SE-AR-000003015

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 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 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	13th January 2023
1 st Surveillance Audit Due	12th January 2024
2 nd Surveillance Audit Due	12th January 2025
Certificate Expiry (subject to the company maintaining its system to the required standard)	12th January 2026

Daniel..

Authorised Signatory

