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 Regulation (EU) 2017/745 on Medical Devices for Class 1.

Certificate No.: CE - 3866

Manufacturer : SASCAN MEDITECH PVT. LTD.

Address : TIMed, MS VALIATHAN BLOCK (5TH FLOOR), SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY (SCTIMST) POOJAPURA P.O., THIRUVANANTHAPURAM - 695012, KERALA, INDIA

Products : ORALSCAN-HAND HELD DEVICE FOR SCREENING, DETECTION AND BIOPSY GUIDANCE OF ORAL CANCER

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Regulation (EU) 2017/745 on Medical Devices for Class 1.

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	10th January 2023
1st Surveillance Audit Due	09th January 2024
2nd Surveillance Audit Due	09th January 2025
Certificate Expiry (subject to the company maintaining its system to the required standard)	09th January 2026

Authorised Signatory

UK Certification & Inspection Ltd.