TRANSASIA®

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UNMATCHED SERVICE
SINCE 1979....

Date : 26.04.2022

Certificate of Conformity and Calibration

TO WHOMSOEVER IT MAY CONCERN

ISO 15189:2012 REQUIREMENTS REGARDING,"CALIBRATION AND VERIFICATION PROCEDURE"

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificates is issued are CE Marked. Transasia Bio-Medicals Ltd , Mumbai ,manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015 .This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assure following

- The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.
- TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.
- All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.
- All TBM products are factory calibrated and final qc passed at the time of release.
- The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed
- Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufactures recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.

Manish Airan

Head Of Quality Department & Regulatory