



Certificate No.  
Date Issued  
Work Order No.  
Client

Equipment Identification |  
Asset ID      Serial Number      Manufacturer

Reference Equipment/s |  
Asset ID      Description      Serial Number      Cal Due

**BITS BIOMEDICAL INC**  
CAL-260-1000-0316  
CAL Due 12 Feb 26  
CAL By MLC

**BITS BIOMEDICAL INC**  
CAL-260-1000-0316  
CAL Due 12 Feb 26  
CAL By MLC

**BITS BIOMEDICAL INC**  
CAL-260-1000-0317  
CAL Due 12 Feb 27  
CAL By MLC

**BITS BIOMEDICAL INC**  
CAL-260-1000-0314  
CAL Due 12 Feb 26  
CAL By MLC

# TRACEABILITY ≠ ACCREDITATION

A White Paper Series on Biomedical Metrology, Calibration, and Trust

**BITS White Paper** • Think About It - S02 •

BITS Biomedical Inc. | *Quality Forward*

Accredited ISO/IEC 17025:2017 Calibration and Testing Laboratory (ANAB ACT-3400)

# WHY CONNECTED MEASUREMENTS ARE NOT THE SAME AS TRUSTED MEASUREMENTS

## The Statement Everyone Makes and Rarely Questions

“Don’t worry, our tools are traceable.”

This is one of the most common assurances in hospitals, laboratories, and technical organizations. At first glance, it sounds reassuring, professional, compliant, and well managed.

However, traceability alone does not answer the key question that auditors, regulators, and decision-makers ultimately care about:

“Can this measurement be trusted?”

Traceability confirms that an instrument has been calibrated against recognized standards. It shows there is a documented link to reference measurements. While this is important, it doesn’t by itself guarantee that the result is accurate, reliable, or suitable for its intended use.

To build real confidence in measurement results, organizations must look beyond traceability and consider how measurements are performed, controlled, and verified in practice.

## What Traceability Actually Means

Traceability is a technical concept.

It refers to the ability to link a measurement result to a recognized reference, typically a national or international standard, through an unbroken chain of calibrations. Each step in that chain is documented and contributes to the overall measurement uncertainty.

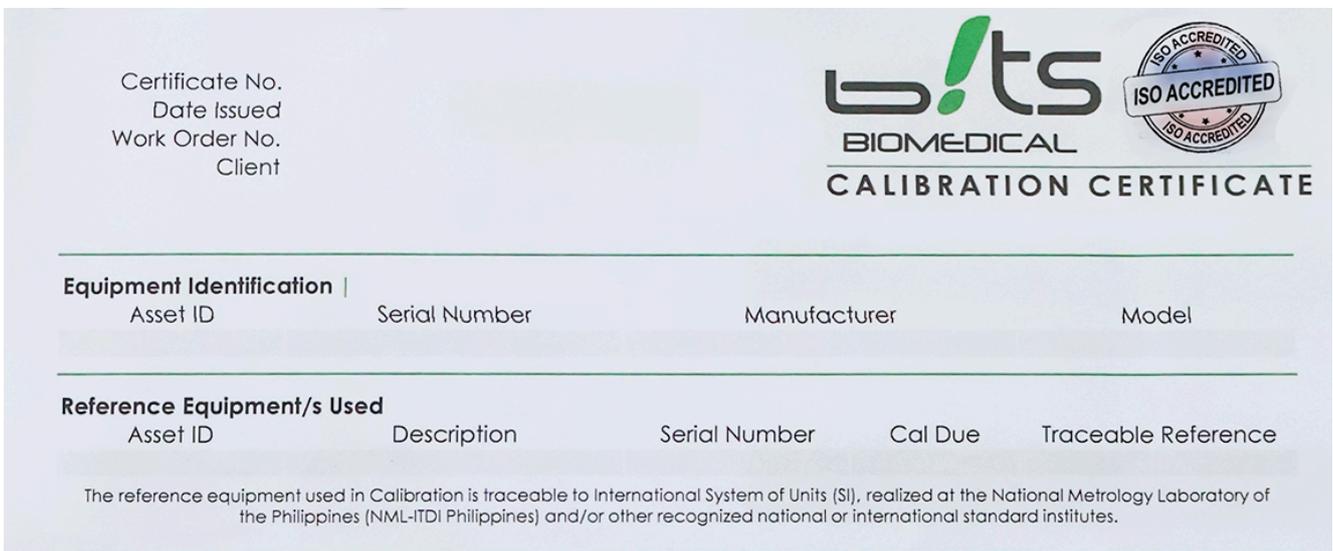
In simple terms, traceability answers one basic question:

“Where does this measurement come from?”

This is important. It provides documented evidence that a measurement is connected to established standards and has been calibrated in a controlled manner.

However, traceability is only the starting point.

*“Traceability connect measurements. Accreditation validates competence.”*



## The Comfort of Traceable Tools

Organizations often invest heavily in:

- Traceable test equipment
- Calibration labels and certificates
- Documented calibration intervals

These are all necessary elements of a sound measurement system. They demonstrate control, structure, and compliance with basic requirements.

However, owning traceable tools doesn't guarantee:

- Correct application of measurement methods
- Proper evaluation of measurement uncertainty
- Competent and trained personnel
- Objective and unbiased results or impartial results

Traceability can exist even when overall measurement quality is weak.

In other words, traceable equipment supports a reliable system, but it doesn't replace the need for proper processes, technical competence, and ongoing oversight.

## Where the Confusion Begins

The misunderstanding often starts with a simple assumption:

*If the tool is traceable, the calibration must be acceptable.*

This assumption is understandable, but it is not correct. Traceability confirms that a measurement is linked to recognized reference through documented calibrations. It shows connections to standards.

It doesn't confirm technical competence, proper execution of the calibration process, or the validity of the results.

Connection alone is not the same as demonstrated capability.

## What Accreditation Adds and Why It Matters

Accreditation, particularly under ISO/IEC 17025, addresses what traceability alone cannot.

An accredited laboratory is required to demonstrate:

- Qualified and authorized personnel
- Validated calibration methods
- Controlled environmental conditions
- Proper evaluation of measurement uncertainty
- Impartiality and independence
- Consistent and transparent reporting

Accreditation answers a different and more practical question:

*"Was this measurement performed competently and impartially?"*

This is why accredited results are formally recognized not only by customers, but also by accreditation bodies and regulatory authorities.

*"Traceability tells you where a result is linked. Accreditation tells you whether it was done right."*

## Why Auditors Look Beyond Traceability

During audits, calibration records are rarely rejected because they lack traceability.

They are questioned because:

- Measurement uncertainty is missing or not justified
- Decision rules are unclear or not defined
- Technical competence cannot be demonstrated
- Independence and impartiality are not established

Traceability confirms that measurement are linked to recognized standards. However, it doesn't address how results are evaluated, how decisions are made, or whether the work was performed competently and objectively.

Accreditation provides the structured oversight needed to address these concerns.

**Traceability Without Accreditation:  
A Risky Comfort**

Relying only on traceable tools or non-accredited calibration can create a false sense of security.

On paper, everything appears properly connected to recognized standards. In practice, confidence is fragile.

When measurements are challenged during audits or regulatory reviews:

- Certificates may be questioned
- Results may be declared invalid
- Recalibration may be required
- Corrective actions may follow

The consequences are often delayed. When they appear, they can be sudden, costly, and disruptive.

**The Right Relationship Between  
Traceability and Accreditation**

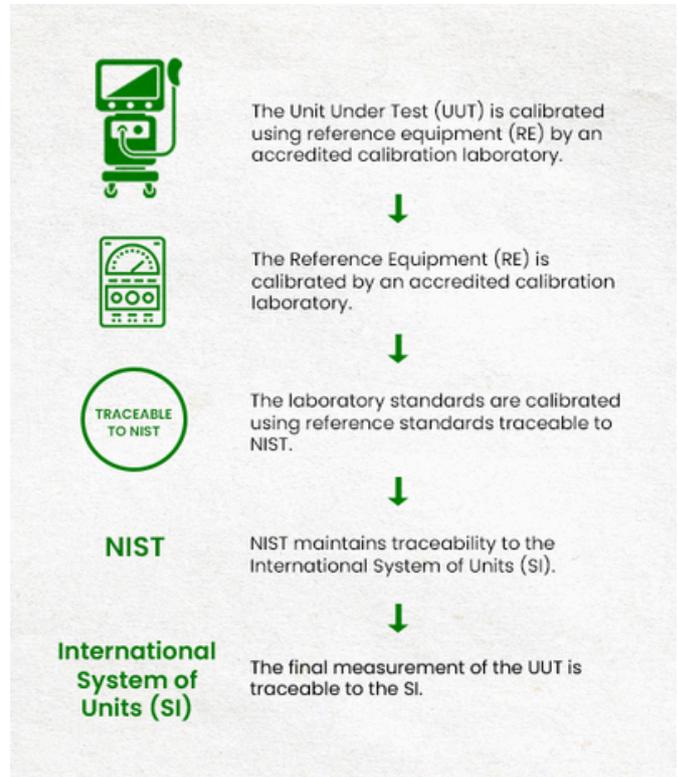
Traceability and accreditation are not competing concepts. They serve different but complementary roles within a measurement system.

- Traceability ensures linkage to recognized standards.
- Accreditation ensures competence, consistency, and trust

Traceability establishes where a measurement originates. Accreditation confirms that the measurement was performed correctly and can be relied upon.

When one exists without the other, the system becomes unbalanced.

Both are necessary to support credible and defensible measurement results.



**What a Balanced Measurement System  
Looks Like**

Organizations with mature quality systems typically:

- Maintain traceable internal tools
- Use traceability for daily monitoring and control
- Rely on accredited laboratories for independent verification
- Clearly document measurement uncertainty and conformity

This balanced approach ensures that the system is both efficient and credible. It combines the practical benefits of traceable tools with the confidence provided by accreditation.

*“Traceability supports measurement. Accreditation supports trust.”*

## Why This Distinction Matters Beyond Compliance

Measurements impact critical outcomes such as:

- Clinical decisions
- Equipment safety
- Regulatory confidence
- Organizational reputation

When traceability is mistaken for accreditation, decisions are made on partial assurance.

Partial assurance is still a risk.

Understanding the difference ensures that decisions are based on results that are not only linked to standards but also performed competently and reliably.



### Think About It:

A traceable result without accreditation is connected, but not confirmed.

## Final Thought

- Traceability shows where a measurement comes from.
- Accreditation shows whether it can be trusted.
- Confusing the two does not save time or money. It only delays accountability and increases risk.



### About the Authoring Organization

This paper is written from the perspective of an ISO/IEC 17025-accredited calibration & testing laboratory actively supporting healthcare institutions, laboratories, and engineering teams in meeting regulatory, accreditation, and patient safety requirements.

The intent is not to replace in-house capability, but to clarify the difference between traceability and accreditation, and to explain where independent assurance is essential and why it matters.

### Preserving Independent Assurance

When calibration must withstand audit scrutiny, independence and competence are critical.

Review which equipment truly requires accredited calibration and align your strategy with clinical risk and regulatory requirements. For guidance on calibration, uncertainty, or audit readiness, consult an ISO/IEC 17025-accredited laboratory.