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NSTDA

สร้างสิ่งแวดล้อมที่ยั่งยืน

ลดความเหลื่อมล้ำ

เพิ่มการเติบโตทางเศรษฐกิจ

เพิ่มการพึ่งพาตนเอง

THAILAND

NET ZERO

NAC2024
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การประชุมวิชาการประจำปี สวทช. ครั้งที่ ๑๙

**Industrial Postdoc/Postmaster :
กำลังคนคุณภาพสูงเพื่อสนับสนุน
อุตสาหกรรมยุทธศาสตร์ของประเทศ**

30 มีนาคม 2567

สำนักงานพัฒนาวิทยาศาสตร์และเทคโนโลยีแห่งชาติ



สอวท
สำนักงานสถาบันนโยบายการอุดมศึกษา
วิทยาศาสตร์ วิจัย
และนวัตกรรมแห่งชาติ

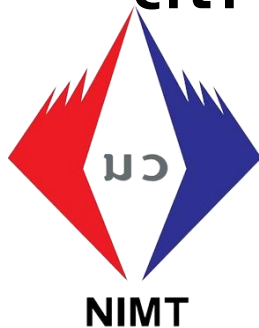


สร้างคน
ข้ามพรมแดน

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NSTDA

Certification of extension tubes for medical use according to TIS 2385-2551

ดร.อริชา กิตติวัฒน์โนคุณ
สถาบันมาตรวิทยาแห่งชาติ





Bever Medical Industry



Product

1. Intravenous → IV Set, Extension Tube
2. Nutrition → Feeding Tube/Bag
3. Catheter → Suction Tube
4. Drainage → Urine Bag
5. Oxygen Therapy
6. Latex Tube





The extension tube delivers medication to the patient by connecting to the other devices such as syringe pump to deliver infused substances or blood components into or out of the body through blood vessels.

Thai Industrial Standards: TIS 2385 – 2551: Extension tube for medical use

International Organization for Standardization:

ISO 8536 – 10:2004 Infusion equipment for medical use – Part 10 :
Accessories for fluid lines for use with pressure infusion equipment

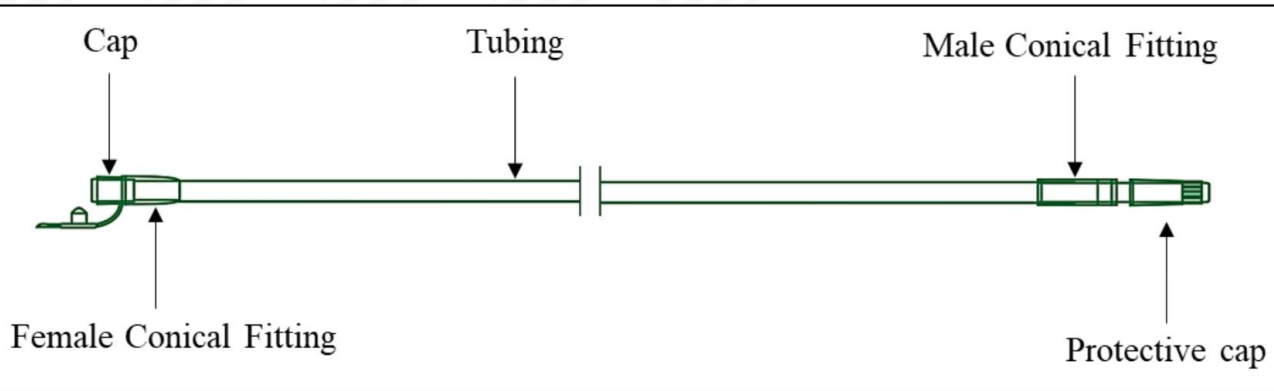


Table 1. Extension tube for medical use manufactured by BMI.

| Size (inch) | Volume (ml) | Length (mm) |
|-------------|-------------|-------------|
| 6 | 0.80 | 152.40 |
| 12 | 1.60 | 304.80 |
| 18 | 2.40 | 457.20 |
| 22 | 2.93 | 558.80 |
| 24 | 3.20 | 609.60 |
| 36 | 4.80 | 914.40 |
| 42 | 5.60 | 1,066.80 |
| 48 | 6.40 | 1,219.20 |

Table 2. Physical properties.

| Test Item | Style | Test Method |
|----------------------|--|---------------|
| Colour | Clear, no black spots | Visual check |
| Tubing | Clean and not defective | Visual check |
| Volume | Depends on length specified on the label | TIS 2385-2551 |
| Length | Depends on the requirement of the client | TIS 2385-2551 |
| Compressive strength | 5 N, 10 sec | TIS 2385-2551 |
| Tensile strength | 15 N, 15 sec | TIS 2385-2551 |
| Leakage | 50 kPa, 2 min | TIS 2385-2551 |



- Various sizes of extension tubes for medical use are manufactured by BMI.
- In this study, an extension tube 12-inch was used as an example for physical testing.



ISO/IEC 17025

Implementing ISO/IEC 17025 as part of laboratory quality initiatives provides both laboratory and business benefits.

KEY BENEFITS OF ISO/IEC 17025

Internationally accepted test and calibration method acceptance level

The validity of the final report

Reliable laboratory – customer relation

Professional working approach and good management

ISO  **17025**
ACCREDITED LABORATORY

ISO/IEC 17025:2017 Compliance Requirements





Objectives

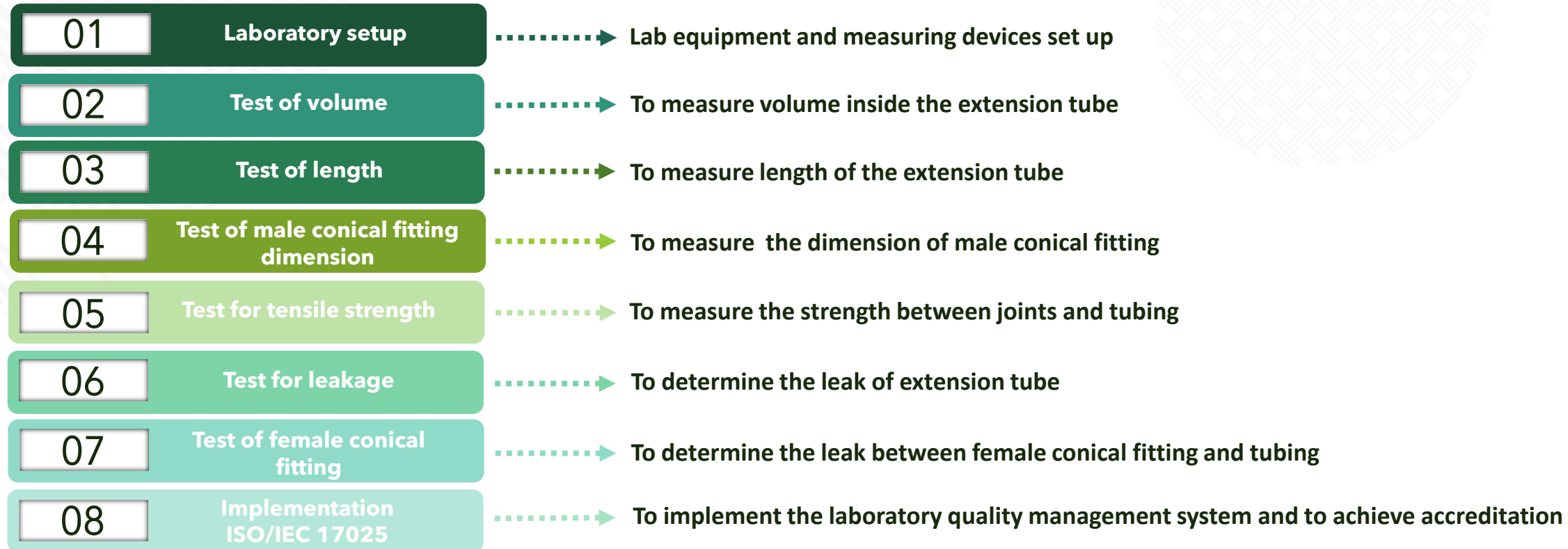


1
To certify the physical test of extension tubes for medical use

2
To implement the laboratory quality management system according to ISO/IEC 17025



Overview of Methods





1. Laboratory Setup



Balance



Steel Ruler



Thermometer



Ring gauge



CRM DI water



UTM

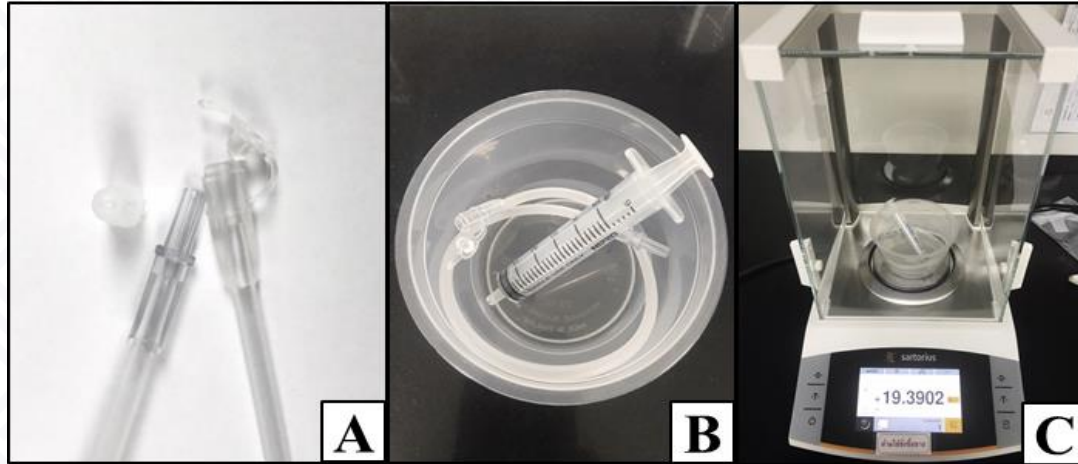


Standard Weight Set

The laboratory has been set up within the production department and controlled in an environment under positive pressure cleanroom conditions to maintain a stable environment for products and operations with relative humidity levels at 50 ± 10 %RH and temperatures at 20 ± 5 °C.



2. Test of Volume



- (A) The cap on female and male conical fitting of the sample were removed.
- (B) The sample and a plastic syringe on a plastic container.
- (C) Weighing the sample and a plastic syringe on a plastic container 3 times.
- (D) Fully injected distilled water from the syringe into the sample.
- (E) Weighing again 3 times and recorded.

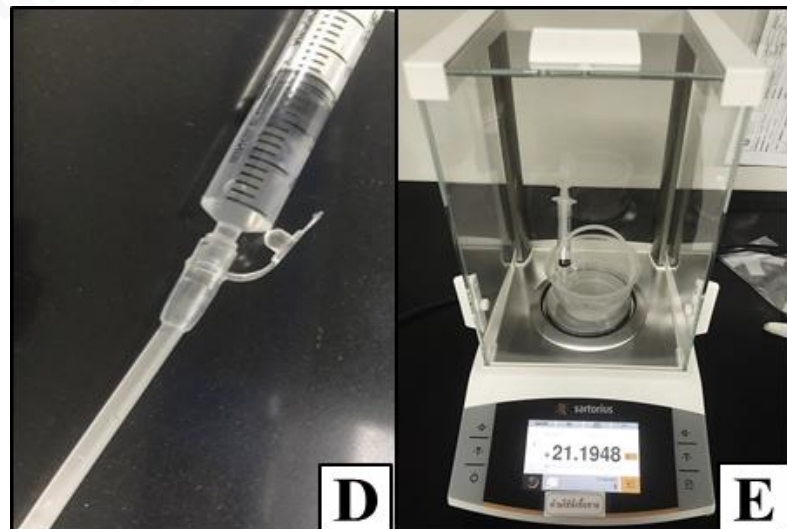


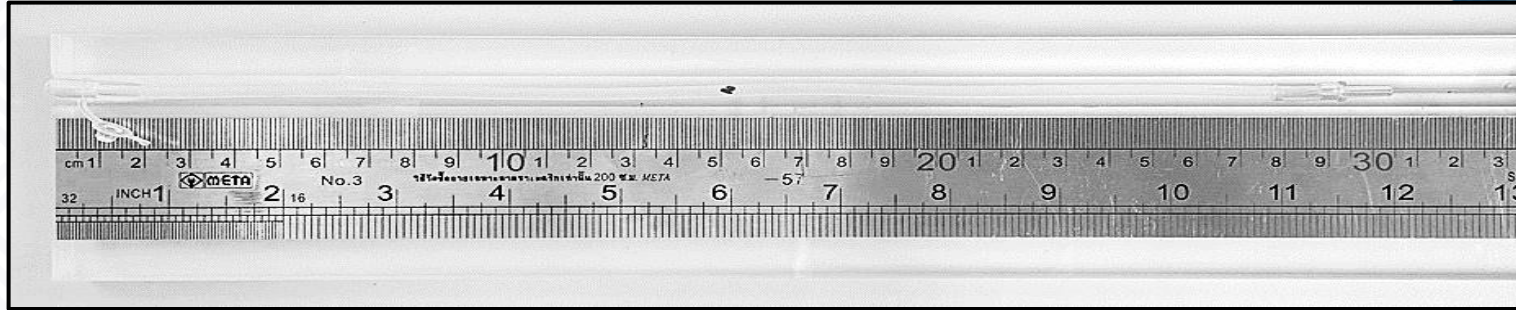
Table 3. Test results of volume on extension tube 12 inch ^a.

| No. of Sample | Volume (ml) | Results | |
|---------------|--------------|---------|--------|
| | | Passed | Failed |
| 1 | 1.612 ± 0.01 | / | |
| 2 | 1.574 ± 0.01 | / | |
| 3 | 1.593 ± 0.02 | / | |
| 4 | 1.656 ± 0.00 | / | |
| 5 | 1.621 ± 0.01 | / | |

^a Volume of extension tube as specified on the label with a percent of error ± 5 (1.60 ± 0.08 ml).



3. Test of Length



The sample was placed smoothly beside the steel ruler.
A cap on female and male conical fitting were removed before measured 3 times and recorded.

Table 4. Test results of length on extension tube 12 inch ^a.

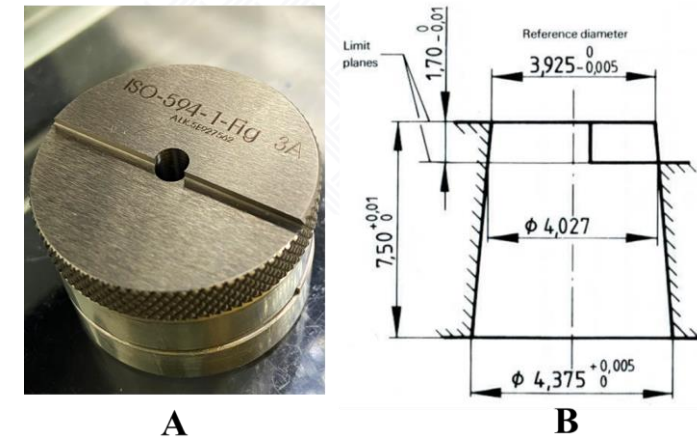
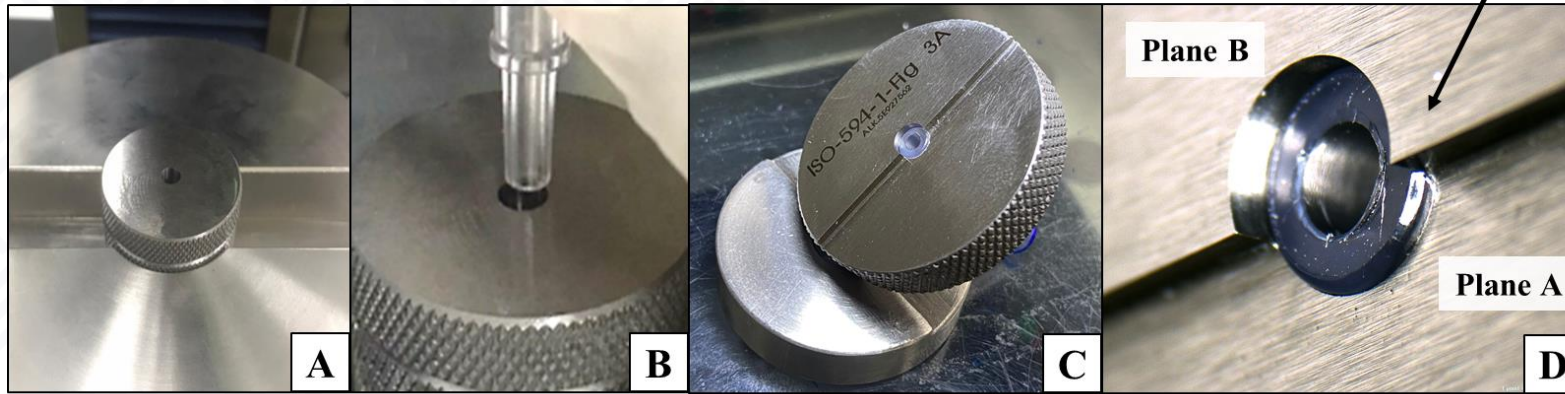
| No. of Sample | Length (mm) | Results | |
|---------------|-----------------|---------|--------|
| | | Passed | Failed |
| 1 | 333.67 ± 0.5774 | / | |
| 2 | 334.67 ± 0.5774 | / | |
| 3 | 335.33 ± 0.5774 | / | |
| 4 | 334.33 ± 0.5774 | / | |
| 5 | 334.33 ± 0.5774 | / | |

^a Length of extension tube as specified on the label with a percent of error ± 10 (304.80 ± 30.48 mm).



4. Test of Male Conical Fitting Dimension

Male conical fitting of extension tube



- (A) A reference gauge was placed on the compression plate.
- (B) The end of male conical fitting was gently loaded in a gauge hole and compressed with a total axial force of 5 N and laboratory specified at ± 0.05 N for 10 sec.
- (C, D) The small end of male conical fitting shall be between the A and B planes of a reference gauge and observed by vision measurement machine.

- Gauge for testing 6% (Luer) conical fitting.
- (A) A reference gauge model ISO 594-1-Fig 3A.
- (B) Drawing of gauge (ISO 594-1)

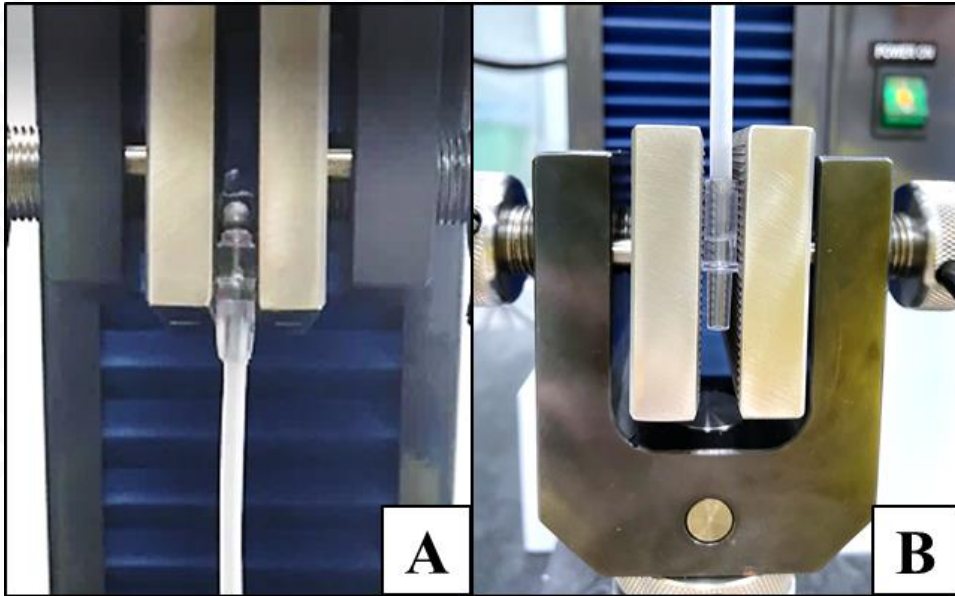
Table 5. Test results of male conical fitting dimension on extension tube 12 inch ^a.

| No. of Test Sample (pieces) | Results (pieces) | |
|--------------------------------|------------------|--------|
| | Passed | Failed |
| 5 | 4 | 1 |

^a The small end of male conical fitting shall be between the A and B planes of a reference gauge.



5. Test for tensile strength



- (A) The female and male conical fitting were applied with UTM on the upper side and lower side.
- (B) Exposed with tensile force at 15 N and specified at ± 0.15 N for 15 sec. All seam welding must not separate from each part .

Table 6. Test results of tensile strength on extension tube 12 inch ^a.

| No. of Test Sample (pieces) | Results (pieces) | |
|--------------------------------|------------------|--------|
| | Passed | Failed |
| 10 | 10 | 0 |

^a All seam welding must not separate from each part by visual check.



6. Test for Leakage



- (A) The container was added with distilled water at 20-30 °C.
- (B) Whole tube was immersed in a water container and applied with an internal air pressure of 50 for 2 min and laboratory specified at ± 1 kPa. The sample was examined for air leakage by visual check.

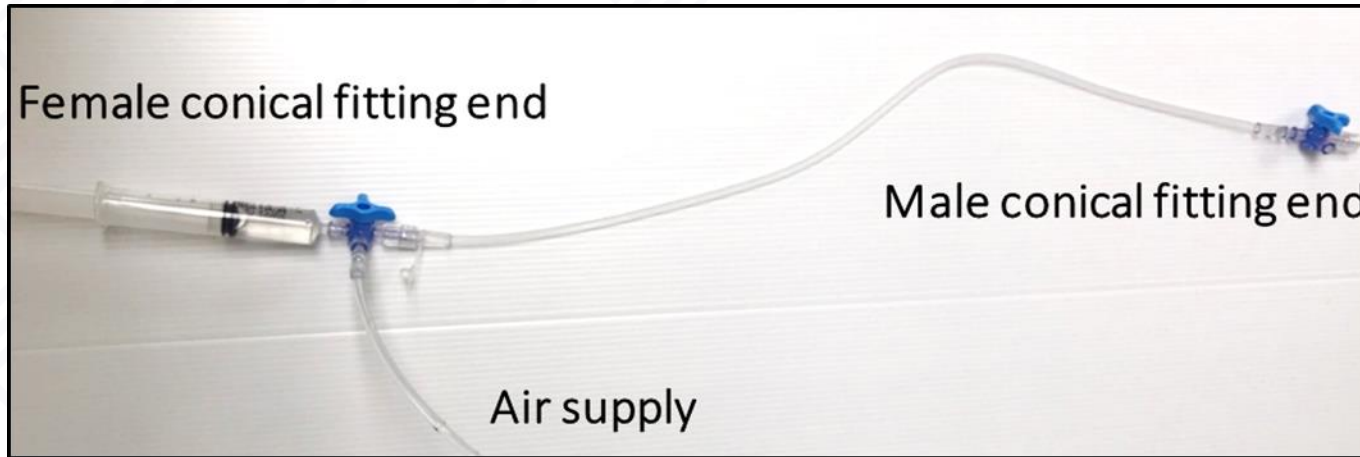
Table 7. Test results of leakage on extension tube 12 inch^a.

| No. of Test Sample (pieces) | Results (pieces) | |
|--------------------------------|------------------|--------|
| | Passed | Failed |
| 10 | 10 | 0 |

^a Examination of air leakage by visual check.



7. Test of Female Conical Fitting



The sample was fully added with distilled water. The end of the male conical fitting was tightly closed. The tubing connected air supply was added with distilled water and opened. Then applied a pressure of 300 ± 10 kPa for 30 sec. The sample was examined for air leakage by visual check.

Table 8. Test results of female conical fitting leakage on extension tube 12 inch ^a.

| No. of Test Sample (pieces) | Results (pieces) | |
|--------------------------------|------------------|--------|
| | Passed | Failed |
| 10 | 10 | 0 |

^a Examination of air leakage by visual check.



8. Implementing ISO/IEC 17025



ISO/IEC17025
Accredited Laboratory

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม
(สมอ.) กระทรวงอุตสาหกรรม

1. Learning ISO/IEC 17025

2. Documentations

3. Assuring the quality of test results

4. Risk and opportunity assessment
and management reviews

5. Internal Audit and External Audit

รับคำขอและตรวจสอบความครบถ้วนของเอกสาร



สรุปรายงานเสนอคณะกรรมการฯ และคณะกรรมการ

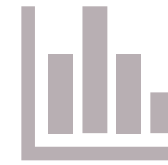


Conclusion

01

Lab Setup

In this study, a 2.5-million-baht was invested for setting up a physical testing laboratory under the clean room conditions and acquiring the measurement equipment.



02

Physical Testing

Six parts of physical test were performed in accordance with requirements specified in the standard TIS 2385-2551.



03

Certification Report

Additionally, we also confirmed that a total of 1.75 million pieces of extension tubes have been certified the quality improvements.



04

ISO/IEC 17025 Implementation

The ISO/IEC 17025 has been implemented under the supervision by NIMT to improve the reliability of testing reports in laboratory activities and to achieve ISO/IEC 17025 accreditation.





THANK YOU FOR YOUR ATTENTION

Contact: Athicha Kittiwattanokhun
Email: athicha91@gmail.com

Certification of extension tubes for medical use according to TIS 2385-2551

**A Kittiwattanokhun^{1,2}, K Naksri², A Keawkaew², D Prakitsuwan²,
T Leeudomwong³ and T Sanponpute^{1*}**

¹ Medical Metrology Laboratory, National Institute of Metrology (Thailand), Pathumthani, 12120, Thailand

² Quality Control Laboratory, Bever Medical Industry Company Limited, Pathumthani, 12130, Thailand

³ Department of Industrial Physics and Medical Instrumentation, Faculty of Applied Science, King Mongkut's University of Technology North Bangkok, Bangkok, 10800, Thailand

*Corresponding author's: tassanai@nimt.or.th

Abstract. The extension tube is a medical device for delivering substances into or out of the body through blood vessels of the patient. To ensure the safety of users and promote the domestic production, the industrial product standard of extension tubes was established as Thai Industrial Standard (TIS) No. 2385-2551: Extension tubes for medical use. Bever Medical Industry (BMI) is a medical device company that manufactures and markets medical supplies for single use. At present, the overall physical requirements standard of extension tubes has not been accredited according to ISO/IEC 17025. This study aims to certify the physical test of extension tubes for medical use and to implement the laboratory quality management system according to ISO/IEC 17025. We set up a laboratory to perform the physical test of extension tubes according to TIS 2385-2551. The measuring equipment was applied appropriately and calibrated by accredited laboratories to ISO/IEC 17025 related to metrological traceability. The established laboratory performed the evaluation of measurement uncertainty for some testing and reported the results to the customer as a test certification report. In this study, a total of 1.75 million pieces of extension tubes have been certified the quality improvements. Therefore, it is valuable for entrepreneurs, importers, and exporters in both domestic and international markets.

ขอขอบคุณผู้ให้การสนับสนุน Industrial Postdoc



Industrial Postdoc/Postmaster : กำลังคนคุณภาพสูงเพื่อสนับสนุนอุตสาหกรรมยุคศาสตร์ของประเทศ

"Industrial Postdoc รุ่น 1, รุ่น 2 และรุ่น 3"

ได้รับงบประมาณสนับสนุนจากกองทุนส่งเสริมวิทยาศาสตร์ วิจัยและนวัตกรรม

โดยหน่วยบริหารและจัดการทุน ด้านการพัฒนากำลังคน และทุนด้านการพัฒนาสถาบันอุดมศึกษา การวิจัยและการสร้างนวัตกรรม (บพค.)

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