UNIVERSITI TEKNOLOGI MARA

INDUSTRIAL TRAINING FIELD REPORT

EPSILON MEDICAL DEVICES SDN BHD

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PROGRAMME	: **DIPLOMA OF CHEMICAL ENGINEERING**
ID	: **2018410008**
LI DURATION	: **23RD MARCH 2021 - 15TH JULY 2021 (17 WEEKS)**

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1.0 INTRODUCTION

Industrial Training in the course code of CHE353 represents a compulsory subject for the Faculty of Chemical Engineering in University Technology MARA. Thus, it is an imperative fundamental in the engineering curriculum. Industrial placement takes part throughout the final semester of the diploma and students are obligated to fulfil 17 weeks of attachments with 7 credit hours. Students are allowed the privilege and choice to pursue any suitable industries across the nation to pursue the training.

The purpose of the industrial training is to train engineering students in the real working environment in chemical manufacturing. Theories gained in all the core and non-core courses can be applied to training by the students. Some of the benefits of industrial training are: observing daily work activities firsthand in a proper setting, gaining the ability to apply technical and theoretical knowledge to industrial problems, direct exposure to nontechnical skills such as oral and written communications, understanding the diversity of the chemical engineering industries, applying computer software programs to real industrial situations, teamwork experiences, time management and deadline objectives, getting familiar with the industrial environment to set and achieve future career goals, working effectively in a multidisciplinary environment, and boosting the student's self-esteem and confidence by gaining today's industrial skills (Ghannam, 2006).

The company that has been chosen for the internship was Epsilon Medical Devices SDN BHD in Kamunting, Perak. The department that being appointed was under Quality Assurance under the supervision of Madam Toheroh Binti Jamaludin the Quality Manager. The internship duration started on 23rd March 2021 until 15th July 2021.

2.0 EPSILON MEDICAL DEVICES SDN BHD

Figure 1: Epsilon Medical Devices SDN BHD Industry

2.1 Overview

Epsilon Medical Devices (EMD) is an established key manufacturer of quality disposable medical devices and components. The company provide Original Equipment Manufacturer (OEM) solutions for well known restorative clients over the world. The company specializes in the services of product development, tool fabrication, validation and qualification, mass production, secondary process, assembly and logistic solutions. Their fundamental products are high-quality medical-grade plastics devices manufactures by injection moulding and extrusion.

Some of the key customers of the company are Teleflex Medical SDN BHD, JABIL, RUSCH Incorporated, SteriPack Asia SDN BHD, Universiti Malaya and numerous more. The products also were distributed outside of the nation such as in the United States of America, France, Germany, Pakistan, China and other Asian countries.

EMD main focus areas are in research & development of medical devices, plastic injection moulding, extrusion, dip forming, Thermoplastic Polyurethane (TPU) blown film extrusion, assembly of medical product and tooling design & fabrication.

The Original Equipment Manufacturer (OEM) products implicate a surgical 3 ply face mask, a coated catheter with water sachet and non-touch sleeve, laryngoscope blade, Haemostatic Delivery System (HDS), Intermittent Fecal Catheter (IFC) and irrigator. EMD also produces Contract Manufacturing (CM) products for instance nasal cannula, speaking valve, insufflation device, trocar and coniotomy tube.

2.2 Motto

Driven by the motto of 'We can make it', EMD strives to be the pioneer of the disposable medical devices industry by exceeding our clients expectations through constant innovation and strict quality control.

2.3 History

EMD is one of the groups under Epsilon Technology SDN BHD that have been founded in the year of 1996 in Penang, Malaysia. The company has established in 2007 and is located at Kamunting, Perak. The aggregate land area remains 65,000 square feet with a total built-up of 50,000 square feet.

2.4 Facilities

The facility of the company involved an injection room that accommodated completely electrically operated injection machines, injection machines with robotic arm dip forming machine and blown film extrusion machine.

Figure 2: Fully Electric Operated Injection Machines

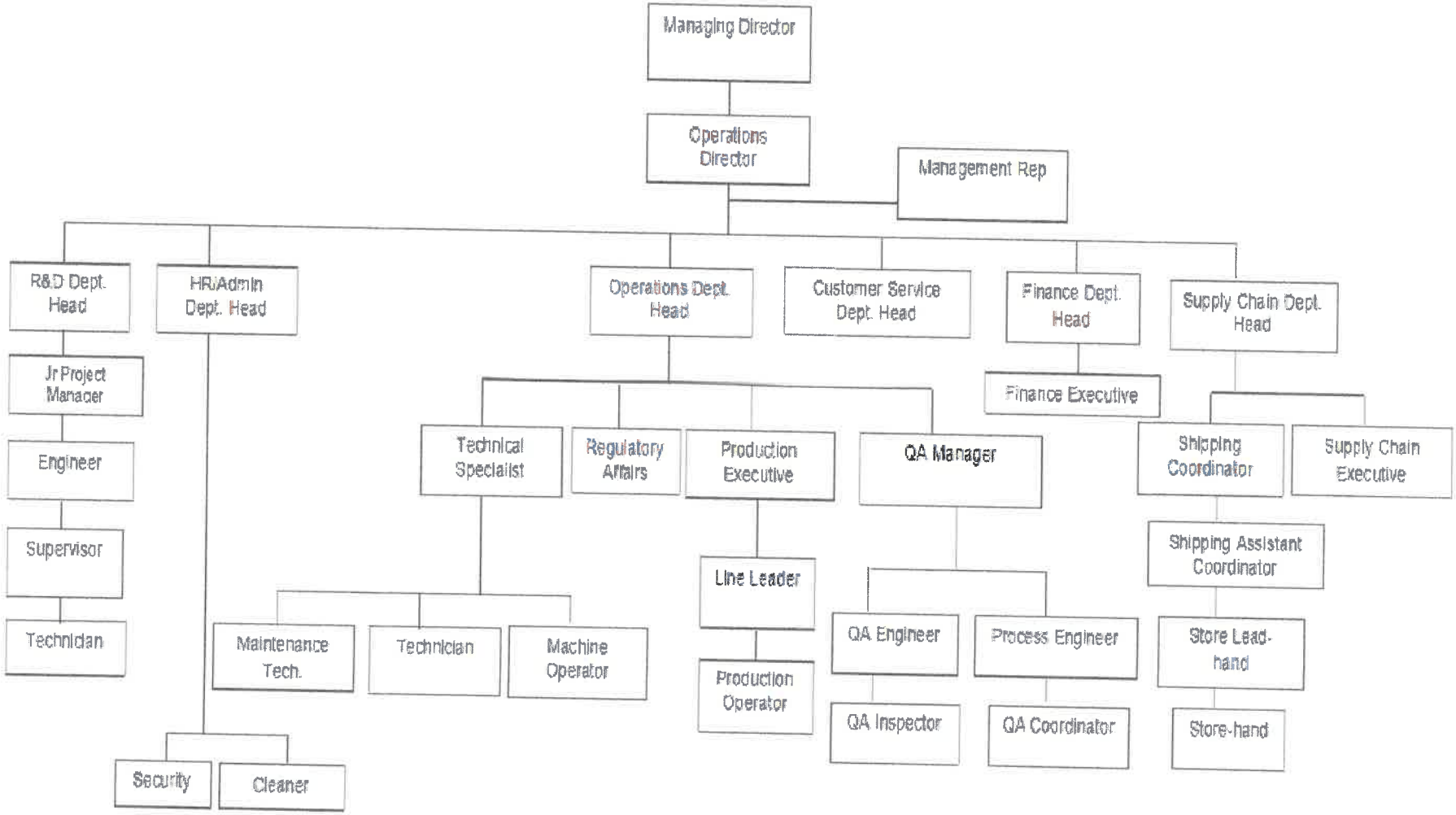
Figure3: Blown Film Extrusion Machine

Another facility is the Class 100K clean room having a 45mm extrusion machine, 65mm extrusion machine, assembly line, form-fill seal machine, hydrophilic coating machine, water sachet filling machine, face mask machine.

Figure 4: Hydrophilic Coating Machine

Figure 5: Water Sachet Filling Machine

2.5 Organization Chart



4.0 PROCESS FLOW

Process Flow of Hydrophilic Coated Intermittent Catheter with Water Sachet

Assembly Machine (Tube Loading)

Loading of catheters could be done automatically or manually.

Fig. 6: Tube Loading Process

Assembly Machine (Eye Punching)

- 2nd eye punching done at this station.
- The machine needs to be set to the required delay forming ,holding time, delay cooling, demould temperature main pressure, gripper pressure, forming speed and forming distance.

Fig. 7: Eye Punching Process

Assembly Machine (Eye Punching)

1st eye punching process will be done at this station.

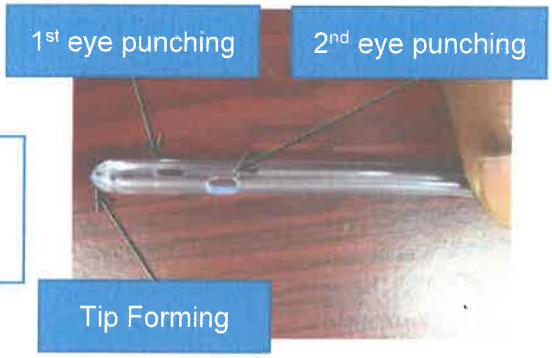


Fig. 8: Catheter Tubing

Assembly Machine (Tip Forming)

- Tip forming process will be done at this station.
- The machine needs to be set to the required time, heating and preheating temperature, hold mode and auto calibration

Fig. 9: Tip Forming Process

Assembly Machine (Funnel Assembly)

- Funnel assembly process will be done at this station.
- The machine needs to be set to the required glue dispense time, pressure, tube clamping and main pressure.

Fig. 10: Funnel Assembly Process

Coating and UV Curing Oven

- Tube priming (Ethanol) and loading will be done at this station.
- The machine needs to be set to the required dip setting, UV setting, conveyor setting

Fig. 11: Coating Process

Unloading and Storage

- Unloading the catheters after completion of coating process and insert non touch sleeve.
- Place the completed catheters into a clean container with close lid.

Loading into Packing Machine

- Load catheter in the formed cavity and place water sachet soft seal end on top of the funnel towards the shaft.
- Ensure products are lay flat into the formed cavity.

Fig. 12: Packing Machine

100% Inspection - Light Test

Inspect the pouches with light test for fundamental matters, product caught in seal and etc.

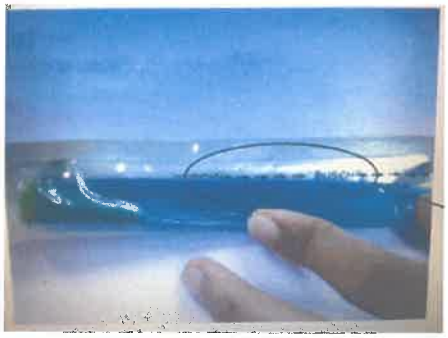


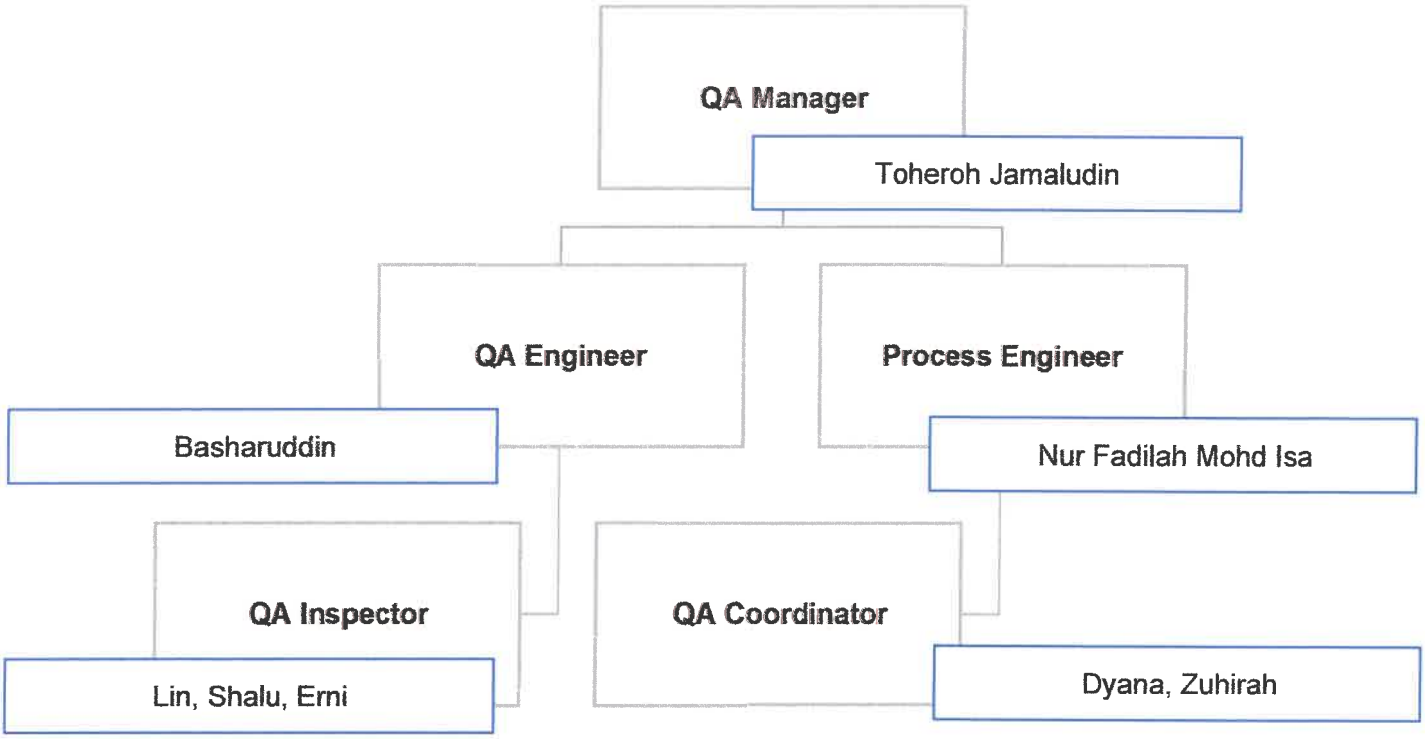
Fig. 13: Inspection Test

Inner Box Packing and Labeling

- Form inner box to shape and affix the respective label.
- Place 30 pieces pouched product into the inner box. Close lid and place into the shipper carton and label

Fig. 14: Packing and Labeling

5.0 QUALITY ASSURANCE DEPARTMENT



5.1 Quality Assurance

The Quality Assurance Department is accountable for compliance effective and successful quality administration framework concurring to the company and ISO 9001 standard, ISO 13485 standard, regulatory and customer prerequisites. It is also responsible for all perspectives of quality control and assurance activities from crude materials and finished products. The department monitor customer complaint on products quality issues and drive cross-function teams and suppliers intending root cause and *inconvenience shooting. It is also liable to execute specifications for the systems of control, inspection,* sampling and test procedures with defined acceptance and rejection limits, including the control of all reports thereof.

5.2 IQ, OQ and PQ

Process Flow of Quality Assurance Protocol for Manufacturing

To create a future development product, the manufacturer needs to follow the procedure of the general requirement validation protocol. Quality Assurance will construct the equipment validation protocol after receiving the appropriate Standard Operation Procedures, manuals, and other information from Production or Research and Development (R&D). As in the quality assurance element, machinery validation is critical to generate consistent and high-quality products. The procedure involved three aspects of protocols which were Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ). These protocols represent mechanisms for illustrating that the equipment being utilized or installed will grant an acute degree of quality assurance such that manufacturing processes will reliably mass-produce products that are appropriate to quality requirements.

Installation Qualification (IQ) is a documented verification that all key aspects of the equipment or system installation follow suitable codes, specification requirements and affirmed design intentions, which manufacturer's recommendations are appropriately studied. The task of assembling information to confirm the installed components or machines are the ones indicated and that they are legitimately distinguished and installed as expressed within the development documents, and following the particular obligation of the user. Followed by FDA-Regulated Industries, an effective IQ regularly incorporates to the location of installing with essential floor space, documentation any computer-controlled instrumentation, gathering all manuals and certifications, properly unloading and cross-checking instruments, analyzing instruments and components for damage, ensuring rectify control supply, installing ancillary instruments, documenting firmware versions and serial numbers, environmental and operating conditions, checking software system installation and accessibility, recording calibration and validation dates of tools utilized for IQ and verifying connections and communication with peripheral units.

After each IQ protocol has been performed, Operational Qualification (OQ) is carried out. OQ define as a documented verification approved by objective evidence that the equipment, system or subsystem achieves as aimed throughout all expected operating ranges and modes which consequence in a product that meets all predetermined requirements. This entails identifying and inspecting equipment elements that may have an impact on the quality of the final output. The activity of testing the various components of the process, system, or equipment to document the fitting execution of these components as distinguished to their predetermined requirements. All components in the test plan are tested during OQ, and their performance is meticulously documented. An adequate OQ usually includes temperature control and variations, pressure and vacuum controllers, temperature distribution, humidity-measuring and control and fan-speed controllers.

Performance Qualification (PQ) is the final phase in the equipment qualification process. PQ protocol is only eligible for equipment or systems that can be assessed in their operational environment to consistently and reliably operate in line with the defined specifications and quality attributes for the intended application. It will cover challenges of dominant factors and worst-case testing. PQ define as a test procedure designed to generate assurance that the process equipment is effective and repeatable. The activity of challenging a system, process or equipment to provide evidence of appropriate and reliable operation as compared to their predetermined requirements. Rather than testing individual components and devices, PQ tests them all as part of a partial or overall process. The team must first construct a

detailed test plan based on the process description before they can begin qualifying. It's vital to remember that the quality of the qualification is mostly determined by the test plan's quality. According to FDA guidance, the following elements should all be included as part of PQ protocols:

- Manufacturing conditions such as equipment limits, operating parameters and component inputs
- A comprehensive list of data that should be recorded or examined during testing, calibration, and validation
- *Tests are performed to guarantee that the quality of the product remains consistent throughout* the manufacturing process
- A sample strategy that specifies the sampling methods to be utilized throughout and between production batches
- Methodology for making data-driven, scientific, and risk-based decisions using statistical data
- Define variability limitations and contingency procedures for dealing with non-conformance.

Quality Assurance will assemble, summarize, and analyse all of the results and generate the final report for the executed protocol after receiving all of the test data sheets and raw data from the Production personnel. QA shall update the Validation Log and file validation report once the validation report has been approved.

5.3 Mini Project

5.3.1 Intermittent Catheter Form-fill and Seal Packing Machine

The production of the form-fill and seal packaging for intermittent catheter will undergo Operational Qualification protocol so that the products will produce necessary documented evidence in accordance with Epsilon Medical Devices procedures and complies with all requirements. Upon the accomplishment of OQ, the form-fill and seal packaging, the products can be demonstrated with established process parameter settings.

There are two types of form-fill and seal packaging products in this operational qualification which were pediatric, male and female. From Table 1, the products can differ with the dimension of the pouch. The measurements consist of pouch length, pouch width, water channel length for placement of water sachet, water channel width, film depth, film thickness after forming and water flow channel length.

Table 1: Packaging Pouch for Operational Qualification

Item	Pouch	Pediatric/Male	Female
Form-fill and seal packaging	Pouch length	500 ± 0.10 mm	260 ± 0.10 mm
	Pouch width	50 ± 0.10 mm	50 ± 0.10 mm
	Water channel length (placement of water sachet)	190 ± 5mm	150 ± 5mm
	Water channel width	15 ± 3mm	15 ± 3mm
	Film depth	11 ± 3mm	11 ± 3mm
	Film thickness after forming	0.08 ± 0.04mm	0.08 ± 0.04mm
	Water flow channel length	270 ± 0.10mm	25 ± 0.10mm
	Seal width	Not less than 6mm	Not less than 6mm

The packaging pouch was produced by a form-fill seal machine in the clean room area. In Figure 15, the machine was shown and the purpose of the equipment is to form, filling and seal the plastic film. The process started when the film melted at the forming station and then passes to the filling station, where the product will load into the plastic. After filling the area, it will undergo the sealing section where the top and bottom web are sealed. The key parameters for the equipment were forming temperature, forming time, forming pressure, sealing temperature, sealing time and sealing pressure.

Figure 15: Form-fill seal machine

After all the processes were completed, the form-fill and seal packaging will undergo the sterilization process. The sterilization method consists of 1xEO and 2xEO. EO or EtO Sterilization is a low temperature method that reduces infectious agent levels by consuming Ethylene Oxide gas. The temperature is typically between 37 and 63°C. Ethylene Oxide is primarily utilized as a gas and is combined with other chemicals like carbon dioxide or steam. It is primarily practised for items like plastic that cannot resist the heat of typical autoclave treatment. Temperature and relative humidity represent the most prominent physical characteristics to observe.

During the OQ phase, process parameters were to be challenged to ensure the product meets the standards under the expected manufacturing conditions. A series of tests were performed on the operation were the lower limit, higher limit, and nominal limit process parameters. This was to demonstrate the process parameters can consistently generate goods that match the specified requirements. Sealing temperature, forming temperature, forming time, sealing time, forming pressure, sealing pressure, forming ventilation, and sealing ventilation are the process parameters that must be validated. The process parameters to be challenged for Operational Qualification of Form-Fill and Seal Packaging are shown in Table 2. A series of tests will be carried out on the product packaging created at the lower and upper limits of the process parameters. The sampling plan shall be applied to each process parameter setting. All the samples will be arbitrarily selected and checked according to the acceptance criteria. The acceptance criteria for the operational qualification are shown in Table 4.

Process Parameter Setting

Table 2: Process parameter setting-Female Form-Fill and Seal packaging

Test Group	Lower Limit	Nominal Limit	Upper Limit
Forming Temperature (°C)	80	90	100
Sealing Temperature (°C)	130	140	150

Table 3: Process parameter setting-Male/Pediatric Form-Fill and Seal packaging

Test Group	Lower Limit	Nominal Limit	Upper Limit
Forming Temperature (°C)	80	90	100
Sealing Temperature (°C)	130	140	150

Test Method and Sampling Plan

- **Dimensions** - each dimension to be tested were measured with a calibrated equipment and the results were recorded. An attribute sampling plan were used to demonstrate with 95% confidence interval and 95% confidence level of the lot meets the acceptance criteria. Actual sample required were 59 but a total of 60 samples were taken for verification.
- **Seal Strength Test** - each sample were tested with Universal Testing Machine and the results are recorded. A variable sampling plan were used to demonstrate at least 30 samples are tested to determine whether it meet the acceptance criteria.
- **Dye Penetration** - sample were evaluated by visual inspection for any leaking of dye from the pouch seal and the results were recorded as pass or fail. An attribute sampling plan were used to demonstrate with 95% confidence interval and 95% confidence level are required. Actual sample required were 59 but a total of 60 samples were taken for verification.
- **Burst Test** - each product packing were tested with Burst tester machine and the results of burst value were recorded. A variable sampling plan were used to demonstrate at least 30 samples were tested to determine whether it meet the acceptance criteria.
- **Ink Adhesion** - printed ink on the pouch were rub with IPA (10x) and the result were recorded as pass or fail. An attribute sampling plan were used to demonstrate with 95% confidence interval and 95% confidence level were required. Actual sample required were 59 but a total of 60 samples were taken for verification.
- **Peel Test** - The pouch was hold at peel open end and gradually peeled the pouch vertically and the result were recorded as pass or fail. An attribute sampling plan were used to demonstrate with 95% confidence interval and 95% confidence level are required. Actual sample required were 59 but a total of 60 samples were taken for verification.
- **Physical Test** - The water sachet was broke and wet the catheter, then the package was tipped end-to-end three to six times. The package was peeled opened at the funnel and the catheter was pulled slowly, the catheter should not stick to pouch upon activating with water.

Table 4: Acceptance criteria for Form-Fill and Seal Packaging

Parameter	Test Method	Sample Size (pcs)	Acceptance Criteria	
			Female	Male
Dimension	Measure with Ruler or Caliper	60	Meets specification as per **Table1**	

Seal Strength	Use the Universal Testing Machine under speed of 300mm/min	30	Not less than 1.2N
Peel Test	Visual Inspection	60	Check for void in seal area, pleated, no or poor lacquer transfer and fiber tear.
Dye Penetration	Visual Inspection	60	Examine the pouch to see if any colored water had seeped through the seal area indicating leak after 10 minutes.
Burst Test	Use Burst tester machine	30	5 to 10 kPa
Bubble Test	Visual Inspection	60	No air bubbles escaping from any area on the pouch for duration of min 5 sec
Ink Adhesion	IPA Rub Test	60	Pouch printing must be legible
Physical test	By hand feel	30	The product should not stick to pouch upon activating with water

All the exceptional conditions, deviations, or other issues were adequately resolved and approved by Management. The operational qualification summary report shall contain a summary of all conducted validation activities and results that were reviewed and approved. Any changes and deviations made to the Operational Qualification of Form-Fill and Seal Packaging were listed and documented. Justification or correction of any missing items or failures were documented in the report. The project team signed off the protocol amendment if there were any qualification changes or inadequacies. The data were collected and recorded in the Operational Qualification Reports as an attachment and were reviewed for compliance with the acceptance criteria. All closure of non-conformance found during the execution of this protocol was documented.

After all the testing was completed, based on the result obtained from this operational qualification, its shows that the pouch produced by form-fill and seal Packing Machine has been fulfilled in terms of dimensional, functional test and mechanical test based on product specification, quality attributes and standards. It also demonstrated that the process parameter setting provides capabilities and is qualified in producing the form-fill and seal pouch for female and male/pediatric. Based on the Operational Qualification results, it shows that the form-fill and seal packaging for female and male/pediatric produced by the form-fill and seal Packing Machine are complied and meet the acceptance criteria. Hence, the machine can be released for the following Performance Qualification process.

5.3.2 Hydrophilic Coated Intermittent Catheter

The Operational Qualification protocol purpose was to specify the specifications and acceptance criteria for coating production for Intermittent Catheters. The successful completion of this OQ will produce the necessary documentary evidence that the coating for the Intermittent Catheter was manufactured in line with Epsilon Medical Devices SDN BHD procedures and bears all standards. It was withal to show that coating for Intermittent Catheter may produce within the parameters of the method. Table 5 shows the *Intermittent Catheter size and dimension chosen in this Operational Qualification.*

Table 5: Intermittent Catheter size and dimension

Product Code	Size	Type	Coating Length (mm)	Overall Length (mm)	Outside Diameter, OD (mm)	Inside Diameter, ID (mm)
FGRM 12FR	12 FR	Male	255 ± 5	405 ± 10	4.0 ± 0.1	2.6 ± 0.1
FGRM 14FR	14 FR				4.7 ± 0.1	3.1 ± 0.1
FGRM 16FR	16 FR				5.3 ± 0.1	3.4 ± 0.1
FGRM 18FR	18 FR				6.0 ± 0.1	4.0 ± 0.1
FGRF 12FR	12 FR	Female	80 ± 5	205 ± 10	4.0 ± 0.1	2.6 ± 0.1
FGRF 14FR	14FR				4.7 ± 0.1	3.1 ± 0.1
FGRF 16FR	16 FR				5.3 ± 0.1	3.4 ± 0.1
FGRF 18FR	18FR				6.0 ± 0.1	4.0 ± 0.1
FGRPP 8FR	8 FR	Pediatric	180 ± 5	250 ± 10	2.7 ± 0.1	1.6 ± 0.1
FGRP 10FR	10 FR				3.3 ± 0.1	2.1 ± 0.1

For the Operational Qualification phase, the process parameters were challenged to ensure the product meets the requirements under the anticipated conditions of manufacturing. Table 6 shows a series of tests were conducted on the lower limit, upper limit and nominal limit of the coating parameters involved in the operations. This proved the process parameters can consistently produce products that comply with the required specification. The samples plan was detailed and applied to each process parameter setting. The sample was randomly selected and checked according to the acceptance criteria. The process parameters and test results were recorded in the report.

Process Parameter Setting

Table 6: Process Setting UV Curing Exposure Time

Parameter Unit	Setting	Pediatric		Male/Female			
		8FR	10FR	12FR	14FR	16FR	18FR
UV exposure time (sec)	Lower	160	160	160	160	160	180
	Nominal	180	180	180	180	180	200
	Upper	200	200	200	200	200	220

Test Method & Sampling Plan

- **Dimension** – sample were tested and were measured with a calibrated testing equipment and the results were recorded. An attribute sampling plan were used to demonstrate with 95% confidence interval and 95% confidence level were required. Actual sample required were 59 but a total of 60 samples were taken for verification.
- **Appearance** – sample were evaluated by visual inspection, feel (sample will evaluated by way of finger feel after 30 secs soaked in RO water) and with red colour water test for any sign of damage or uneven coating on catheter surface and the results are recorded as pass or fail. An attribute sampling plan were used to demonstrate with 95% confidence interval and 95% confidence level were required. Actual sample required were 59 but a total of 60 samples were taken for verification.
- **Physical** – sample were measured the friction value or cycle or friction (COF) of the coated catheters by using the friction tester V2.0 The coating should exhibit equivalent or better performance than the competitors' samples. The actual friction value was recorded. A variable sampling plan were used to demonstrate at least 30 samples were tested to determine whether it meet the acceptance criteria. The sample were measured the performance of hydrophilic coating after being activated with RO water and leave at the ambient temperature at 1 minute, 5 minutes, 10 minutes and 15 minutes. The dry out time (DOT) should be equivalent or better than the competitors' samples. The actual dry out time was recorded. A variable sampling plan were used to demonstrate at least 30 samples were tested to determine whether it meet the acceptance criteria.

Table 7: Acceptance Criteria for Intermittent Catheter

Parameter	Test Method & Tools	Sample Size (pcs)	Acceptance Criteria
Dimension	Inside Diameter (ID) measure with Smart Scope	60	Meets specification as per **Table 5**
	Outside Diameter (OD) measure with Smart Scope		

	Overall Length (OL) measure with Ruler		
	Coating Length with Ruler		
Appearance, Feel and Red Colour test	Appearance and Feel are evaluated by way of finger feel after 30 secs soaking in Reverse Osmosis (RO) water	60	The surface should feel smooth, homogeneous and without uneven parts.
	Red colour adherence test evaluated by soaking the coated catheter in color water for 30 secs.		The surface of coated catheter MUST be evenly distributed by the RED dye a cross the coated length. There should not be any patches or uneven distribution or adherence.
Physical	Friction Test	30	Friction Value (COF) - to measure the friction value of the coated catheters by using the friction tester V2.0. The coating should exhibit equivalent or better performance than the competitors' samples.
		30	Dry out time (DOT) - to measure the performance of hydrophilic coating after being activated with RO water and leave at the ambient temperature at 1min, 5mins, 10mins and 15mins. The dry out time should be equivalent or better than the competitors' samples.

The accomplishment from all the testings for Intermittent Catheter shown it has been fulfilled the product specification, quality attributes and standards. It is also demonstrated that the process parameter setting demonstrates capabilities and is qualified in producing Intermittent Catheter for sizes CH8, CH10, CH12, CH14, CH16 and CH18. Hence, the machine can be released for the subsequent process (Performance Qualification).

6.0 CONCLUSION

For the past 17 weeks having industrial training in Epsilon Medical Devices SDN BHD, I have undoubtedly gained so many experiences, knowledge and skills. Being appointed in Quality Assurance Department conveyed to me a grasp and understanding of the importance of quality control and assurance of products. Every product from the raw material until finishing need to be careful and thorough tested and inspected before run in the production and release to the markets. I was exposed to the process of the developing new products, *managed documentation of validation protocols*, *handled machines such as Universal* Testing Machine and Friction Tester Machine, and understood some part of mechanism in industrial medical devices from management, production, technical, quality and shipping department. I have taken chances to observe the real situation and environment that happened in the manufacturing company. Other than that, I developed tremendous skills including products knowledge of medical devices, testing, computer skills in Microsoft Office and software machines, adaptability, attention to detail on doing the testing and inspection, data entry, filing and paper management, and machine learning. I have earned trustworthiness to handle the products testing on my own and prepared documentation. I was active listening on orders given out by the supervisor, accessing and analyzing information also established commitment. Regarding my interaction skills, all the staffs in EMD were sociable and kind despite their ages and races. This helped to boost my communication skills as the intern student.

To conclude, the purpose of industrial training was achieved as it showed the student was capable to dive in industrial working surrounding and profits with all the knowledge and skills. Consequently, the scope discovered Quality Assurance department was much related to the course undertaken by the student which was CHE227 Product Design and Development in semester 5 of Diploma in Chemical Engineering. It benefits to practise and sharpen the theories received in classes into the training.

7.0 Reference

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Steris. (2020, August 17). Anatomy of an ethylene oxide sterilization process. STERIS AST. https://www.steris-ast.com/techtip/anatomy-ethylene-oxide-sterilization-process/

8.0 APPENDICES

Products from the mini project

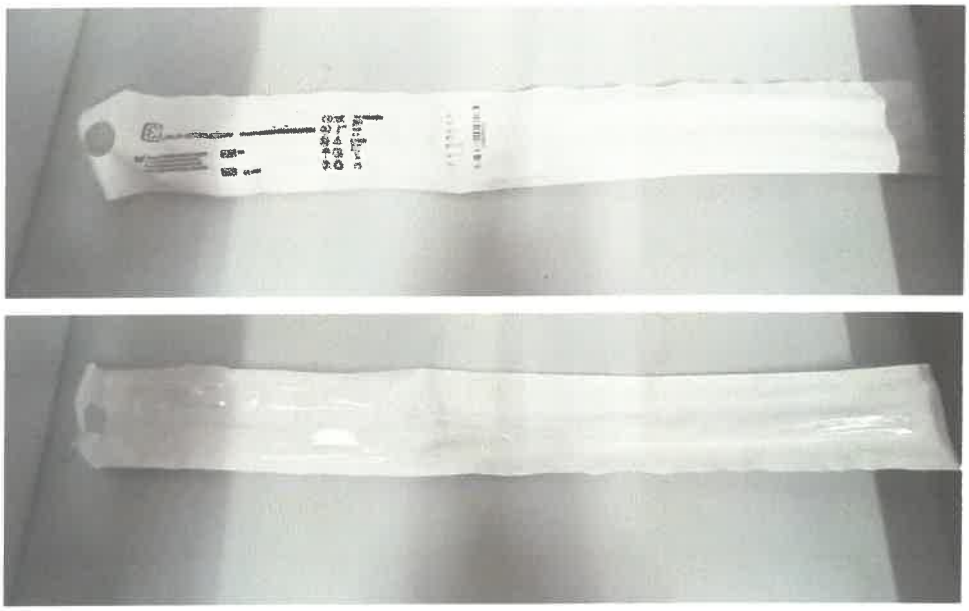

Figure 16 & 17: Pouch packaging for Intermittent Catheter from Form-fill and Seal Packing Machine

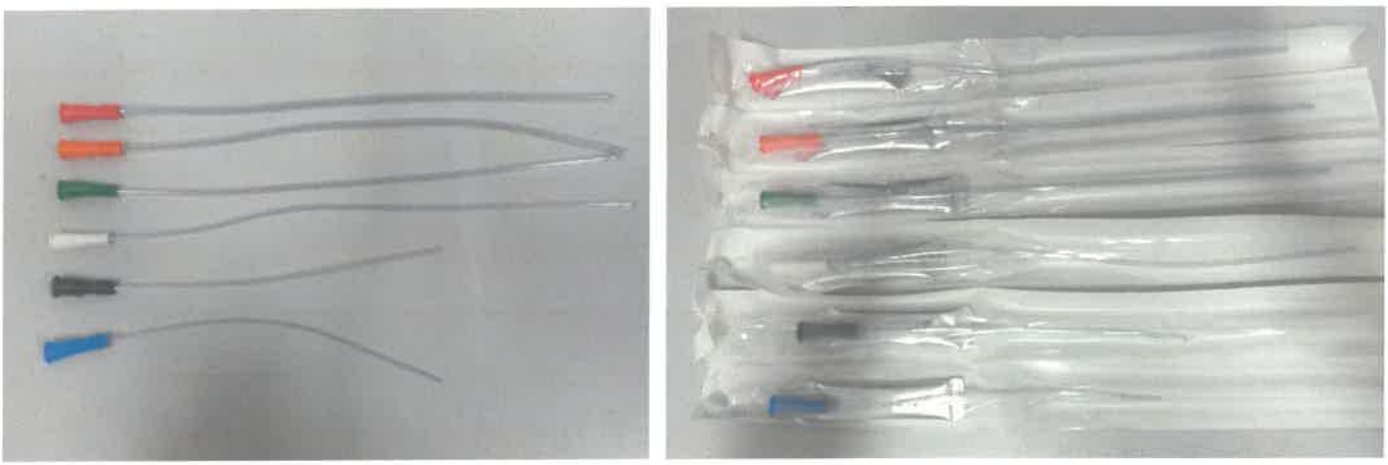

Figure 18: Hydrophilic Coated Intermittent Catheter (from the top size 18FR Male, 16FR Male, 14FR Male, 12FR Male, 10FR Pediatric and 8FR Pediatric)

Figure 19: Pouched Hydrophilic Coated Intermittent Catheter with non-touch sleeve and water sachet

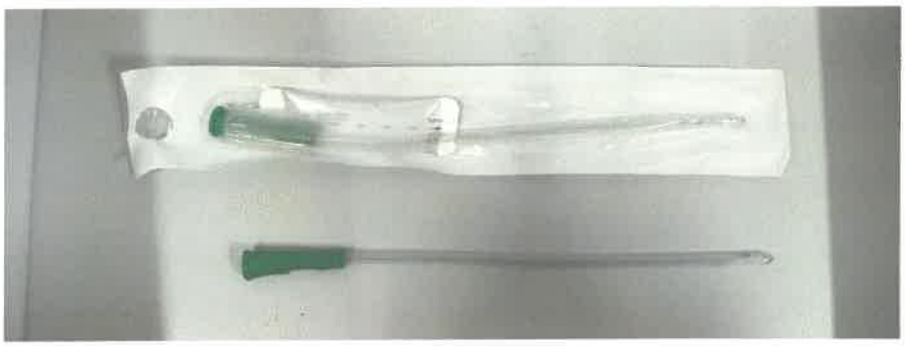

Figure 20: Hydrophilic Coated Intermittent Catheter size 14FR Female

Figure 21: Water Sachet for 8mL (Female) and 10mL (Male)

Equipment from the mini project

Figure 22: Thickness Gage and Caliper

Figure 23: Burst Tester Machine

Figure 24: Universal Testing Machine

Figure 25: Friction Tester Machine

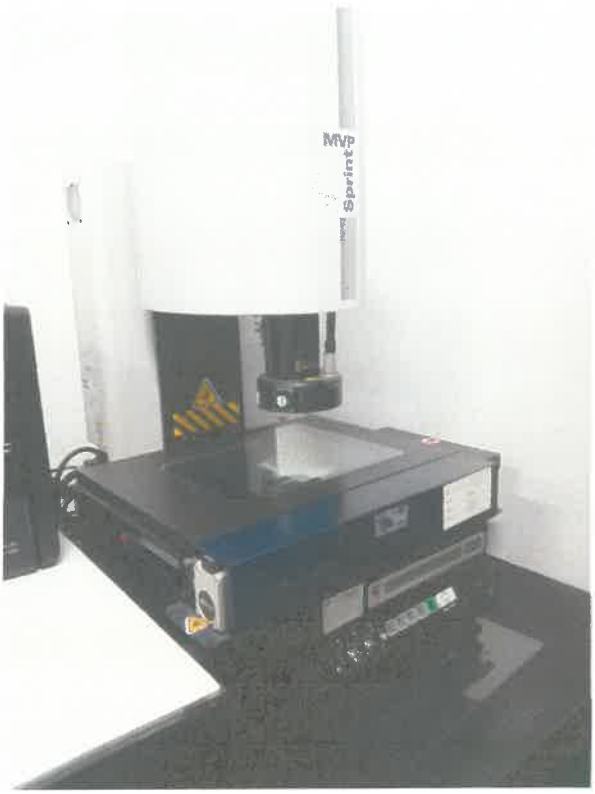

Figure 26: Smart Scope Machine

Industrial Training Student Logbook

Pouch Packaging (male) for intermittent catheter at Forme-fill and seal packing machine

Thickness gage and caliper

STUDENT WEEKLY PROGRESS REPORT

Effective from 23/3/2021 to 26/3/2021

Day	Description of practical training experience / Details of project(s)
Tuesday 23/3/2021	- Company introduction by HR department - Do inspection on pouch (male) using setting 1 x ETO1 warning letter on blister pack packaging
Wednesday 24/3/2021	- Do inspection on pouch (male) using setting 1 x ETO1 for parameter of width, length, outer channel length, outer channel width, blind depth, inner flow channel, thickness, seal width and its adhesion (shape cut, peel test)
Thursday 25/3/2021	- Do inspection on pouch (male) high setting (1 x ETO) - Do inspection on pouch (male) low setting (1 x ETO) for 3 set
Friday 26/3/2021	- Do inspection on funnel for nasogastric, suction catheter (male) low setting (1 x ETO) for size 10Fr, 12Fr, 16Fr - Do inspection on pediatric size pouch, low setting (1 x ETO)

Type(s) of skills obtained:
- learn how to use caliper and thickness gage (Technical skills)
- doing reminder to medical products (product knowledge, skills)

Name of mentor/supervisor : PUAN ROHAYU BT JAMALUDDIN

Comment(s)

Signature of mentor/supervisor : Rohayu

Figure 27: Week 1 (23/3/2021 - 26/3/2021)

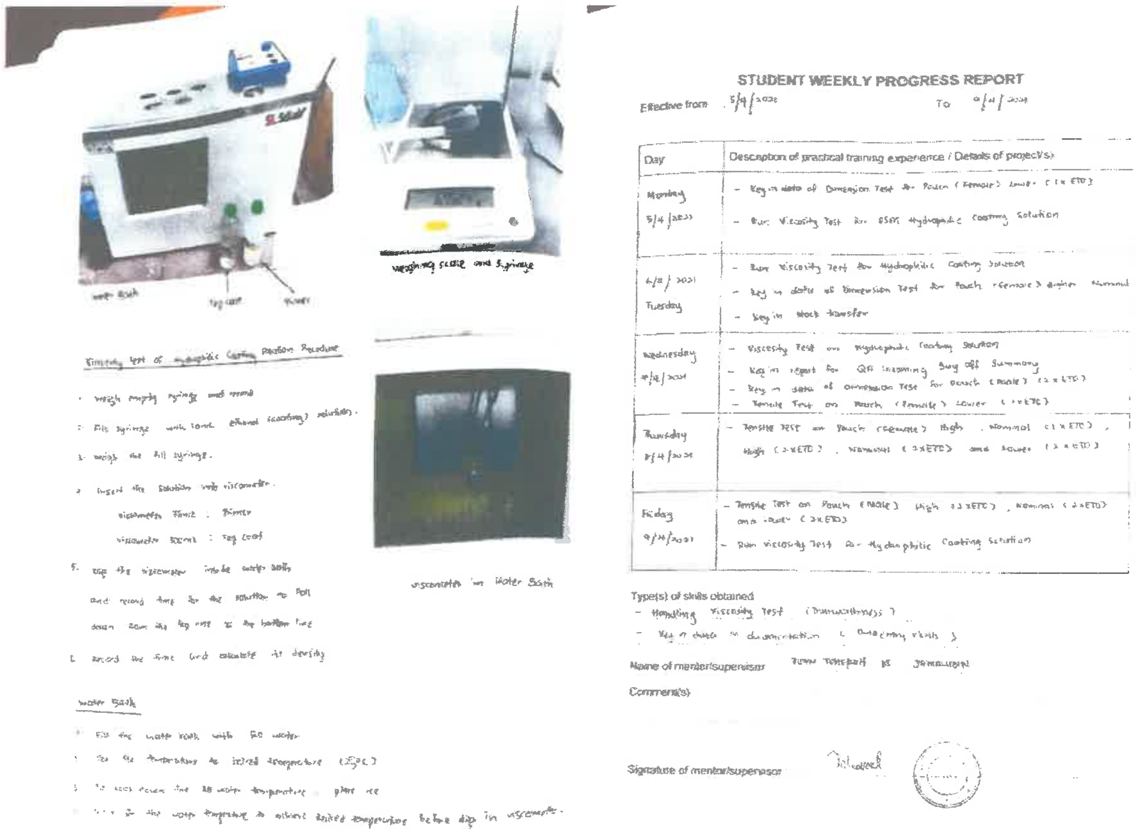

Figure 28: Week 3 (5/4/2021 - 9/4/2021)

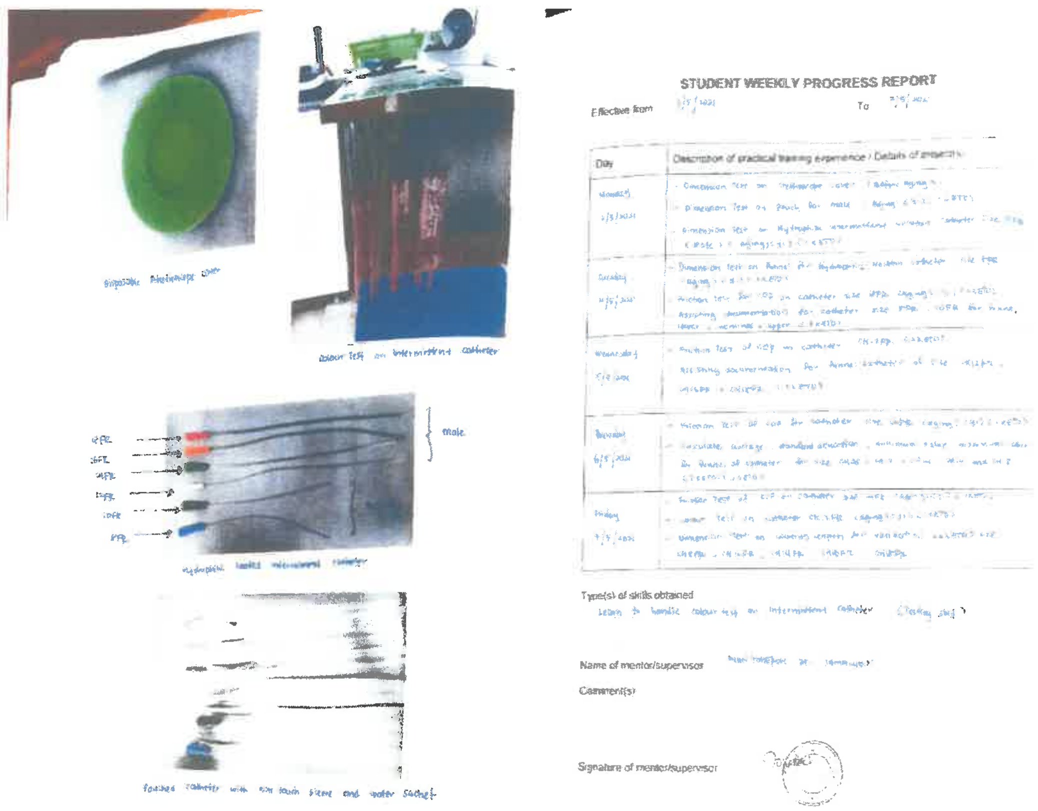

Figure 29: Week 7 (3/5/2021 - 7/5/2021)