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Original Article

Development of halal medical devices in Malaysia: Recommendation and challenges

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ABSTRACT

The medical device industry is one of the important industries in the world, which is now growing rapidly with an estimated market growth rate of about 10 percent annually. In 2012, the value of global market for medical devices was USD307.7 billion, while the market in Malaysia is expected to grow by 15.9 percent annually and reached USD2.8 billion by the year 2017. There are more than 180 manufacturers of medical devices in Malaysia involved in the production of sophisticated products such as orthopedic products, surgical instruments and dialysis machines. Recently, local companies experience the trend towards complying with internationally recognized quality standards such as ISO13485 as an attempt to penetrate the global market. However, there is a religious need to provide medical devices that are certified halal in order to cater to the needs of Muslim consumers who make up 64.3% of the Malaysian population. Therefore, this article will discuss the trend of medical device industry in Malaysia, recommendations and challenges in the development of halal medical devices. The article focuses on the application of surgical sutures that frequently implanted in the human body compared with other medical devices. This study discovers that there are two major challenges in the medical device industry namely, (i) lack of law on halal which specifically subjected to the medical devices, and (ii) halal aspect is not mentioned in the present medical device standard to guarantee the quality of products in order to compete globally.

Keywords: medical devices, suture, halal, Malaysia, healthcare

Introduction

Issues on halal certification have become one of the main concerns among consumers. Recently, there has been discussions on the halal need for medical device products. The medical device sector plays an important role in healthcare aspect.[1]

"Medical devices" encompass all areas of medical equipment from the computer with sophisticated technology to the simplest tongue depressor made of wood. The

[1] Thirumalai, S. and Sinha, K.K. "Product Recalls in the Medical Device Industry: An Empirical Exploration of the Sources and Financial Consequences," *Management Science* 57(2): 376-392, doi:10.1287/mnsc.1100.1267.

intended primary mode of action of a medical device on the human body is different with medicinal products, as it does not involve metabolic, immunological and pharmacological reactions.[2] The Malaysian medical device industry produces a wide range of medical device products include medical gloves, implantable devices, orthopedic equipment and dialysis machines, other invasive surgical equipment, dental, optical and public health.

Definition and classification of medical device

Based on ISO 13845, "medical device" refers to any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or related article, intended by the manufacturer to be used alone or in combination, for human beings for one or more of the specific purposes of:[3]

i. Diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

iii. Investigation, replacement, modification, or support of the anatomy or of a physiological process;

iv. Supporting or sustaining life;

v. Control of conception;

vi. Disinfection of medical devices;

vii. Providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Each country has its own definition to classify the medical devices, whether based on its design, intended use and the level of potential risk to the human body. The regulatory authority is responsible to monitor the classification of the medical device.[4] The medical devices in Malaysia are divided into four classes as shown in Table 1.

[2] Cheng, M., *Medical Device Regulations: Global Overview and Guiding Principles*. (Geneva: World Health Organization, 2003). Available at: http://www.ncbi.nlm.nih.gov/pubmed/21530908.

[3] Sharples, S., Martin, J., Lang, A., Craven, M., O'Neill, S. and Barnett, J., "Medical Device Design in Context: A Model of User-Device Interaction and consequences," *Displays* 33(4-5) (2012): 221–232, doi:10.1016/j.displa.2011.12.001.

[4] Global Harmonization Task Force, "Principle of Medical Device Classification," *Obstetrics and Gynecology* 123 (2012): 30, doi:10.1097/01.AOG.0000443274.83522.9a.

Table 1

Classification of Medical Devices

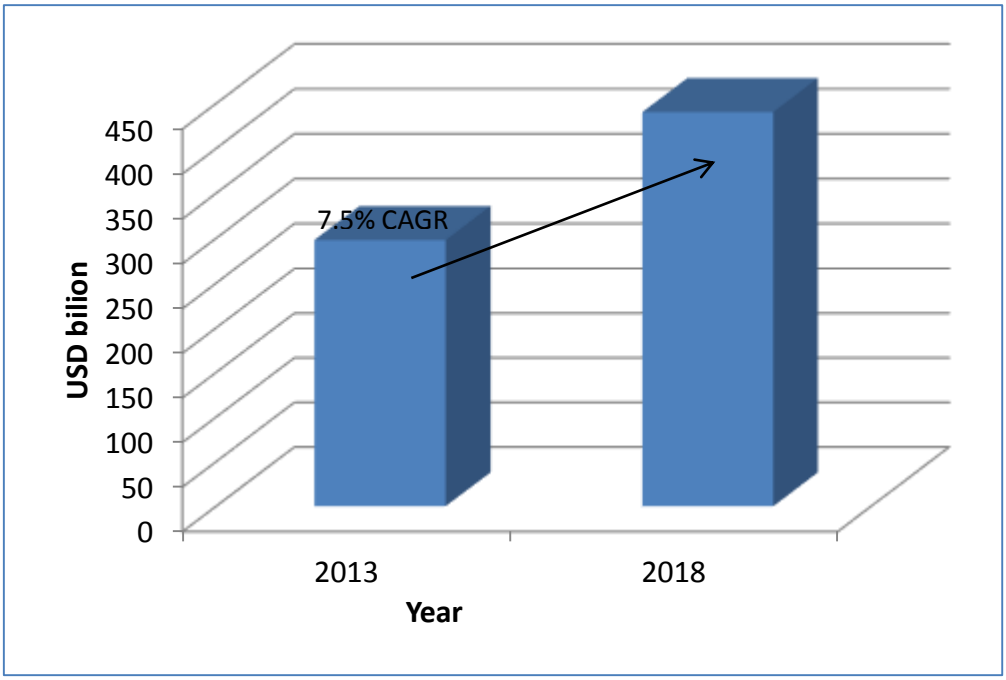
Class	Level of Risk	Example of Devices
A	Low hazard	Bandages, tongue depressor
B	Low moderate hazard	Hypodermic needles, suction equipment
C	Moderate-high hazard	Lung ventilator/non-absorbable suture
D	High hazard	Heart valves/ implantable device

Recommendation on the development of halal medical devices

The medical device market is not static as it increases in accordance to the medical field. The global medical device market in 2013 is valued at USD298 billion, and is projected to experience an estimated annual growth rate by 7.5% and reaches USD440.5 billion by 2018 as shown in Figure 1.[5]

Figure 1

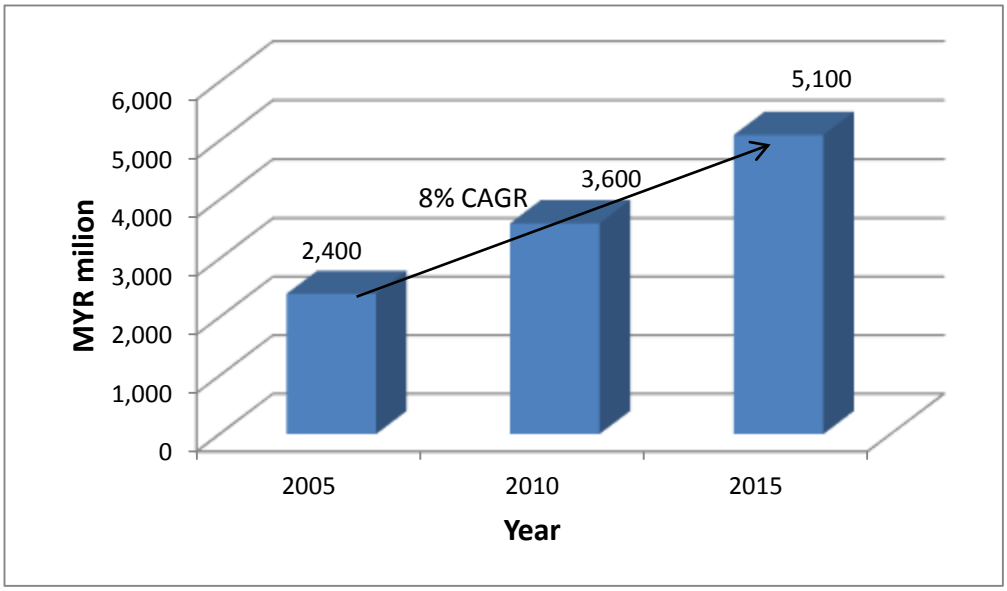
Global Market Size for Medical Devices



Meanwhile, the medical device market in Malaysia has increased by up to eight percent per year since 2005, and is expected to reach MYR5,100 million by 2015 as shown in Figure 2.

Figure 2

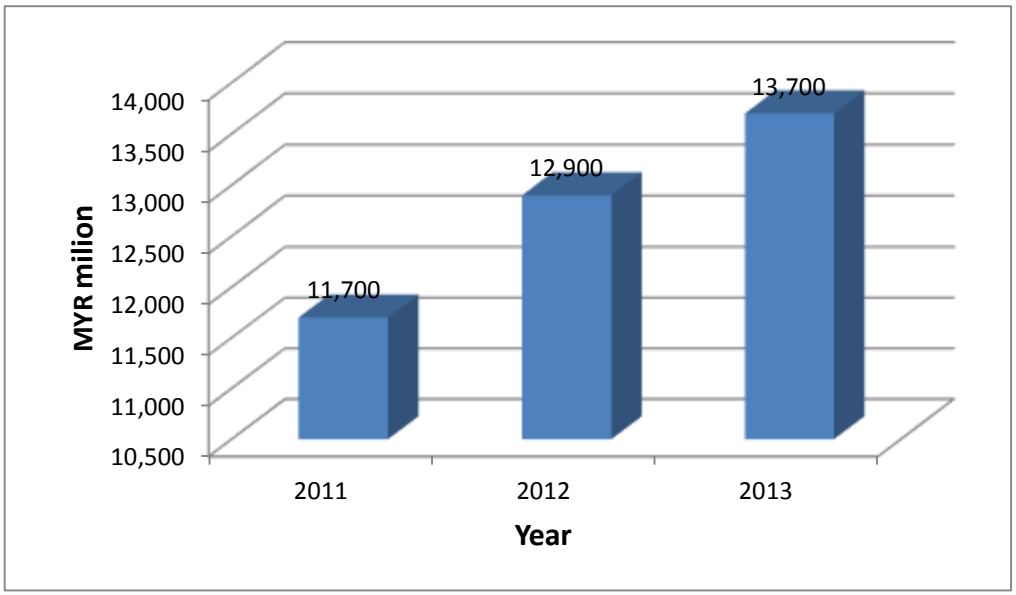
Malaysian Market Size for Medical Devices



Market review on the export of medical devices in Malaysia shows a consistent improvement of MYR11,700 million in 2011 and reached MYR13,700 million in 2013 which can be seen in the following Figure 3.

Figure 3

Export of Medical Devices from Malaysia (2011-2013)



[5] Association of Malaysian Medical Industries, *Medical Device Industry Outlook Report 2013: Achieving Global Excellence*. (Penang: AMMI, 2013).

The scenario in Malaysia shows that this industry is dominated by small and medium enterprises (SMEs) engaged primarily in the production of medical gloves and other disposable medical products.[6] However, the involvement of SMEs are mainly in the production of a wide variety of non-rubber based products such as plastics, silicon, metal and implant products.[7]

Overall, there are more than 180 medical device manufacturers in the country, consisting of three different structures in terms of targeted market (both domestic and international markets), and its compliance to the international standards. Malaysia shows a convincing potential in the medical device industry during the Arab Health 2014 healthcare exhibition in Dubai International Exhibition Centre, United Arab Emirates (UAE) with the participation of 32 Malaysian companies. Surgical sutures, *in vitro* equipment and an endotracheal tube attract a number of countries like India, Pakistan, Egypt, Oman, Saudi Arabia, Iran, China, UAE, Germany and Turkey to import these products from Malaysia.

Surgical sutures

Surgical suture is a biomaterial device that is used to ligate blood vessels and approximate tissues separated by surgical or traumatic wounds. It is made up of either natural or synthetic sources. Although there are many techniques to treat mechanical injuries such as staples, tape and adhesives, suture stitching is a tool that is widely used.[8] Suture production registered a tremendous growth stimulating within the last two decades and become the largest group of biomaterials with a huge market over USD1.3 billion annually.[9]

Surgical sutures belong to the category of active therapeutic device, which is a type of active medical device that can be used independently or in combination with other equipment to support, modify, replace or restore biological functions or structures with for the purpose of treatment and minimize injuries. Specifically, non-absorbable sutures, implants and other long-term invasive surgical equipment are categorized in Class C. Normally, the class C devices are used in orthopaedic, dentistry, ophthalmic and cardiovascular treatments. Meanwhile, absorbable sutures belong in Class D, i.e., devices that give rise to biological effects or being absorbed entirely or partially when use. "Biological effect" refers to the effect arising from the use of the device intentionally (non-spontaneous) and unintentionally (spontaneous). "Absorbable" refers to the decomposition of material in the body and removal of metabolic products from the body due to decomposition. Class D also includes medical devices that incorporate animal and human tissue.[10]

[6] Joshi, H., "Global Scenario and the Medical Device Industry in Malaysia," 2013. Available at: http://www.mida.gov.my/env3/index.php?page=detailevent&pid=108.

[7] Izatul Hamimi Abdul Razak, Shahrul Kamaruddin, Ishak Abdul Azid and Indra Putra Almanar. "ISO 13485:2003: Implementation Reference Model from the Malaysian SMEs Medical Device Industry," *The TQM Journal* 21(1) (2009): 6-19, doi:10.1108/17542730910924718.

[8] Pillai, C.K.S. and Sharma, C.P. "Absorbable Polymeric Surgical Sutures: Chemistry, Production, Properties, Biodegradability, and Performance," *Journal of Biomaterials Applications* 25(4) (2010): 291-366, doi:10.1177/0885328210384890.

[9] Alan, B.F., Boothby, M. H. and Richards, D. P., "New Sutures and Suture Anchors in Sports Medicine," *Sports Medicine and Arthroscopy Review* 14(3) (2006): 177-184, doi:10.1097/00132585-200609000-0001.

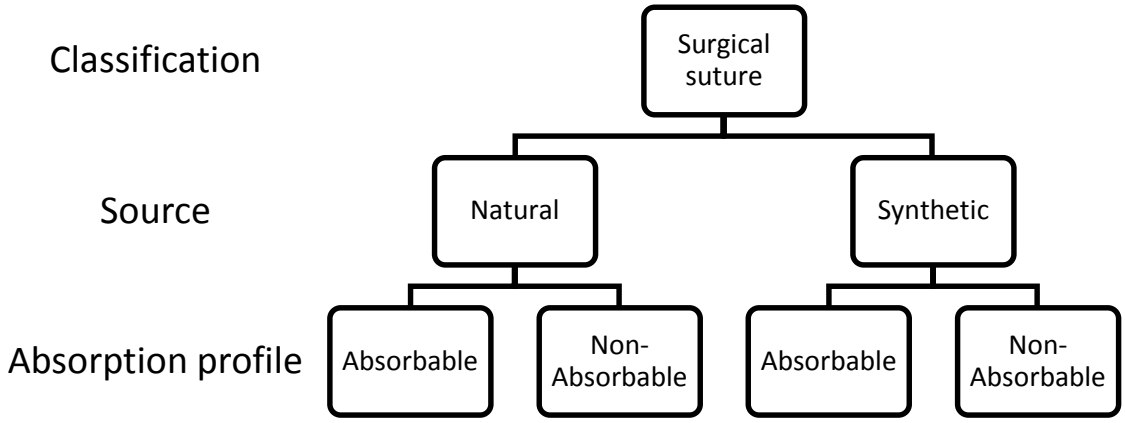
[10] Global Harmonization Task Force, "Principle of Medical Device Classification."

There are two aspects to consider in classifying the sutures.[11] First, based on the source of origin of the suture, either it is natural-based suture or synthetic suture. Synthetic sutures are produced from synthetic polymers such as polyglycolic and polyester. However, natural-based sutures made up of either plant (*nabati*) or animals (*hayawani*). Various findings have shown that sutures are produced from a variety of animal and plant sources. Previously, sutures are made from pig bristles, horsehair, animal guts, wool, beef tendon, deer, rabbits, kangaroos and whales.[12] Although several studies on evaluation of the content of suture material have been published, there were no serious attempts on a comprehensive study on the production, properties, and degradability of sutures. In addition, DNA content of the suture materials have never been analyzed though halal testing.

The second classification divides sutures into two groups according to their biological degradation properties, i.e. absorbable and non-absorbable.[13] Sutures that undergo rapid degradation in tissue, losing their tensile strength within 60 days, are considered absorbable sutures. On the other hand, sutures that generally maintain their tensile strength for longer than 60 days are non-absorbable sutures.[14] Figure 4 illustrates these classifications.

Figure 4

Classification of Sutures



[11] Pillai and Sharma, "Absorbable Polymeric Surgical Sutures."
[12] Pillai and Sharma, "Absorbable Polymeric Surgical Sutures."
[13] Pereira, J.L.P., Viera Júnior, G., de Albuquerque, L.A.F., Mendes, G.A.C., Salles, L.R., de Souza, A.F.F., Dellaretti, M. and de Sousa, A.A., "Skin Closure in Vascular Neurosurgery: A Prospective Study on Absorbable Intradermal Suture versus Nonabsorbable Suture," *Surgical Neurology International* 3 (2012): 94, doi:10.4103/2152-7806.99941.
[14] Tajirian, A. L. and Goldberg, D. J. "A Review of Sutures and Other Skin Closure Materials," *Journal of Cosmetic and Laser Therapy* 12(6) (2010): 296–302. doi:10.3109/14764172.2010.538413.

The consumption of animal-based products are strictly regulated, especially when it comes to religious considerations.[15] Animal-based materials give rise to two polemics, the source of product comes from non-halal animals like pork derivatives and the applications of modern slaughter equipment for halal animal. According to the Department of Islamic Development Malaysia (JAKIM), halal slaughtering process involves restraining, stunning (if used) and severing of trachea, esophagus and both the carotid arteries and jugular veins.[16] Thus, the development of the medical device industry particularly in the production and application of animal-based devices should include the issues of halal and haram.

Development of halal industry for medical devices

The world Muslim population close to two billion and is expected to represent 27% of the global population by 2030. Two major factors that drive halal growth and potential are the growing economic development and disposable income in Muslim countries.[17] Malaysia consists of multiracial and multireligious communities where approximately 62% of the populations are Muslims with the remaining 38% are non-Muslims.[18] Today, the issue of halal receives increasing concerns from both Muslims and non-Muslims due to several factors such as, clean, safe environment and humane slaughtering process.[19] Halal is recognized as a benchmark that guarantees safety, hygiene and quality by Muslim and non-Muslim consumers.[20]

Halal certification refers to the official recognition issued by an authorized body like JAKIM for the proper practices of preparation, slaughtering, cleaning, handling, and management. In order to receive halal certification of a product, the manufacturer must obtain the halal logo and halal certificate as a proof that the product approved in Islam. The products with halal certificate meets the requirements of Islamic, and also acts as a symbol of quality. Hence, halal certification assists in developing the domestic and global market as the potential for halal market is indeed huge, and is beneficial to manufacturers and marketers of halal products.[21]

Concern towards halal status is not only restricted on the final production and application, but should cover the production throughout the entire supply chain, from breeding to retailing. With the number of Muslims now approaching to a quarter of the

[15] Hanzaee, K.H. and Ramezani, M.R., "Intention to Halal Products In The World Markets," *Interdisciplinary Journal of Research in Business* 1(5) (2011): 1-7.
[16] Department of Islamic Development Malaysia, *Malaysian Protocol for the Halal Meat and Poultry Productions*. (Putrajaya: Department of Islamic Development Malaysia, 2011).
[17] Farouk, M. M., "Advances in the Industrial Production of Halal and Kosher Red Meat," *Meat Science*, 95(4) (2013):805-820, doi:10.1016/j.meatsci.2013.04.028.
[18] Department of Statistics Malaysia, *Banci Penduduk dan Perumahan Malaysia*. (Putrajaya: Department of Statistics Malaysia, 2010).
[19] Aziz, Y.A. and Chok, N. V., "The Role of Halal Awareness, Halal Certification, and Marketing Components in Determining Halal Purchase Intention Among Non-Muslims in Malaysia: A Structural Equation Modeling Approach," *Journal of International Food & Agribusiness Marketing* 25(1) (2013): 1-23, doi:10.1080/08974438.2013.723997.
[20] Nik Maheran Nik Muhammad, "Positioning Malaysia as Halal-Hub: Integration Role of Supply Chain Strategy and Halal Assurance System," *Asian Social Science* 5(7) (2009): 44-52. doi:10.5539/ass.v5n7P44.
[21] Aziz and Chok, "The Role of Halal Awareness."

world's population, it is hardly surprising that the halal industry has a significant impact on the global market.

This halal market force is induced by several factors. Firstly, most of the Muslim countries are in the phase of development where they begin to have an impact on the global market, either as producers or consumers. Secondly, the popularity of halal products is indeed increasing among non-Muslims, intensifying the rapid growth of the halal industry and influencing the world. Obviously, halal is not seen as solely a religious issue, but a global symbol of quality assurance and lifestyle choice. Studies by the Halal Industry Development Corporation (HDC) show that increasing acceptance of halal products not only among Muslims, but also non-Muslims. Presently, the halal market has emerged as a most lucrative and influential market in the world.[22]

Global halal market is estimated to be worth USD580 billion annually. Integration, sophistication of science and technology as well as continuous improvement facilitate wide range of high quality of halal products. The Government of Malaysia provides full support in promoting the halal certification process on products and services. Subsequently, Malaysia has developed halal certification that cover quality of health, hygiene procedures for slaughtering process and other operations. The manufacturer of halal product must comply with the standards such as Good Manufacturing Practice (GMP), Good Hygiene Practices (GHP), and ISO to meet the needs of halal.[23] Halal authentication should not be limited to only food, but should be extended to other aspects which include cosmetic, pharmaceutical and medical device products.

Malaysian halal standards prove the government potential as a model in halal management globally. Since Muslims constitutes the largest population in Malaysia, standardization of halal products will be really helpful to Muslim consumers. However, the determination of halal status are dependent on authorized body such as JAKIM to check the halal status for them.[24] Thus, halal certification system of a product aid in increasing the confidence in business, customers, suppliers and shareholders when the product is halal and comply with Shariah requirements.

Challenges in halal development of medical devices

Every country regulates medical devices using its own legal framework.[25] The World Health Organization (WHO) requires that each country to have a policy for dealing with any element involving medical devices, including security, quality, affordable products, use and disposal procedures.[26] Policy will not be successful until it is translated into law. The regulation for the medical device industry is important because it can address the issue of public health and safety. In other words, matters of concern to society will be regulated by enforcement of laws.

[22] Nik Maheran, "Positioning Malaysia as Halal-Hub."
[23] Aziz and Chok, "The Role of Halal Awareness."
[24] Zalina Zakaria. Tapping into the World Halal Market: Some Discussions on Malaysian Laws and Standards. *Shariah Journal* 16 (2008): 603–616. Available at: http://e-journal.um.edu.my/filebank/published_article/2603/945.pdf.
[25] Czajka, R., "Development of Medical Textile Market," *Fibres and Textile in Eastern Europe* 13(1) (2010): 13-15.
[26] Cheng, *Medical Device Regulations.*

At present, Malaysia has the Medical Device Act 2012 (Act 737) and the Medical Device Authority Act 2012 (Act 738) enacted on 9 February 2012 with rules effective from 13 July 2013 with a transition period until July 2015. However, the Descriptions Act Trade 2011 (Act 730) does not cover the medical device.

The Medical Device Act, 2012 (Act 730) provides a mandatory framework for the registration of medical devices in Malaysia as well as guidelines that cover the aspects of application, handling, installation, testing, accreditation, maintenance and disposal of medical devices. However, this act does not mention halal aspect of medical devices used.

The Medical Device Authority Act 2012 (Act 738) provides for the establishment of the authority to regulate medical devices, medical device industry, activities, as well as law enforcement and other related matters.

Meanwhile, the provisions related to the halal certification, the Trade Descriptions Act 2011 (Act 730), which replaced the previous act adopted the Trade Descriptions Descriptions Act 1972, do not cover the medical device.

In February 2005, Malaysia decided to start regulating medical devices to harmonize its regulations and standards with those of other Asian and developed countries.[27] In 2008, the Ministry of Health Malaysia developed the Medical Device Bureau (MDB) to conduct medical device regulatory programmes such as issuing licenses to manufacturers, distributors, importers and exporters, and monitoring of medical devices in the market. MDB also monitors the operation and application of medical equipment, including disposal procedures; laboratory testing and formulating laws and standards.

In July 2003, ISO 13485: 2003 was established to focus on the safety and efficiency of medical devices produced by emphasizing the need of prescriptive documentation.[28] Biological evaluation and test of medical devices are conducted to determine the potential for toxicity or toxins caused by direct or indirect contact between the materials of medical devices with the human body. The tests on the side effect specifically on the biological response of the device involves experiments.

Conclusion

Malaysia is fully committed to strengthening the Halal industry and achieving the vision of making Malaysia a global Halal Hub. At present, various halal aspects have become a concern in the production and application of various products. These halal aspects include meat products, cosmetics products, pharmaceutical products, as well as services such as banking, finance and tourism.

Unfortunately, halal certification for medical devices has yet to be discussed intensely either in the literature or in the public. This is most definitely an area that requires extensive research and discussion involving the various stakeholders of the medical device industry.

[27] Izatul Hamimi Abdul Razak, Shahrul Kamaruddin, Ishak Abdul Azid and Indra Putra Almanar. "ISO 13485:2003: Implementation Reference Model from the Malaysian SMEs Medical Device Industry," *The TQM Journal* 21(1) (2009): 6-19, doi:10.1108/17542730910924718.
[28] Izatul Hamimi et al., "ISO 13485:2003."

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