**ส่วนที่ 7**

**หลักการสำคัญเกี่ยวกับความปลอดภัยและสมรรถนะการทำงาน**

**7. หลักการสำคัญเกี่ยวกับความปลอดภัยและสมรรถนะการทำงานของเครื่องมือแพทย์และวิธีการที่แสดงถึงความสอดคล้อง (Essential Principles of Safety and Performance of Medical Devices and method used to demonstrate conformity)**

*จัดทำเป็นภาษาอังกฤษ ยกเว้นกรณีผลิตในประเทศให้จัดทำเฉพาะภาษาไทย*

*7.1 ให้นำเสนอในรูปแบบของตารางแสดงความสอดคล้องกับหลักการสำคัญเกี่ยวกับความปลอดภัยและสมรรถนะการทำงานของเครื่องมือแพทย์ (Essential Principles of Safety and Performance of Medical Devices) ซึ่งในตารางประกอบด้วยหัวข้อหลักจำนวน 19 ข้อ ในจำนวน 19 ข้อนี้ ผู้ผลิตหรือเจ้าของผลิตภัณฑ์ต้องทราบว่าข้อใดเกี่ยวข้องหรือไม่เกี่ยวข้องกับผลิตภัณฑ์ของตน โดยระบุในคอลัมน์ “Applicable to the device”*

*กรณีข้อที่เกี่ยวข้อง ให้ระบุว่า “Yes” คือ “Applicable”*

*กรณีข้อที่ไม่เกี่ยวข้อง ให้ระบุว่า “No” คือ “Not applicable” และต้องอธิบายเหตุผลว่าทำไมไม่เกี่ยวข้อง*

*7.2 ผู้ผลิตหรือเจ้าของผลิตภัณฑ์ต้องทราบว่าข้อที่เกี่ยวข้อง อ้างอิงมาตรฐานอะไรเพื่อแสดงความสอดคล้อง โดยระบุในคอลัมน์ “Method of conformity”*

*กรณีที่อ้างอิงมาตรฐานระหว่างประเทศหรือมาตรฐานอื่นใด เพื่อแสดงความสอดคล้อง ให้ระบุชื่อเต็มของมาตรฐานดังกล่าว หมายเลขของมาตรฐาน วันเดือนปีหรือปีของการประกาศใช้มาตรฐานและหน่วยงานจัดทำมาตรฐาน*

*กรณีผู้ผลิตหรือเจ้าของผลิตภัณฑ์ใช้มาตรฐานภายในของผู้ผลิตซึ่งพัฒนาขึ้นมาเอง (Product owner/In-house test method) ให้ระบุรายละเอียดของมาตรฐานนั้นๆ*

*กรณีที่มาตรฐานที่ใช้อ้างอิงไม่ใช่มาตรฐานปีล่าสุด ให้ผู้ผลิตหรือเจ้าของผลิตภัณฑ์แสดงความแตกต่างระหว่างมาตรฐานที่ใช้อ้างอิงกับมาตรฐานปีล่าสุด (Gap analysis) ว่าการเปลี่ยนแปลงไม่ส่งผลกระทบต่อความปลอดภัยและสมรรถนะการทำงานของผลิตภัณฑ์*

*7.3 ผู้ผลิตหรือเจ้าของผลิตภัณฑ์ต้องแสดงหลักฐานที่เฉพาะเจาะจงที่แสดงความสอดคล้องในข้อที่เกี่ยวข้อง โดยระบุในคอลัมน์ “Identity of specific documents”* *เช่น ใบรับรอง (certificates) เลขที่, รายงานการทดสอบ (test reports) เลขที่, รายงานการศึกษา (study reports) เลขที่ เป็นต้น ซึ่งหลักฐานที่เฉพาะเจาะจงที่อ้างถึงเหล่านี้จะถูกแนบ โดยเป็นส่วนหนึ่งของส่วนที่ 9.1 การศึกษาก่อนการทดลองทางคลินิก (Pre-clinical studies)*

คำอธิบายส่วนที่ 7 หลักการสำคัญเกี่ยวกับความปลอดภัยและสมรรถนะการทำงานของเครื่องมือแพทย์และวิธีการที่แสดงถึงความสอดคล้อง (Essential Principles of Safety and Performance of Medical Devices and method used to demonstrate conformity) นำเสนอเป็นตารางที่ต้องกรอกรายละเอียด ซึ่งมีหลักการสำคัญอยู่ 19 ข้อ โดยแต่ละข้อมีคอลัมน์ที่ต้องกรอก คือ Applicable to the devices, Method of conformity, Identify of specific documents โดยมีตัวอย่างดังนี้

7. ตารางแสดงหลักการสำคัญเกี่ยวกับความปลอดภัยและสมรรถนะการทำงานของเครื่องมือแพทย์และวิธีการแสดงความสอดคล้อง (Essential Principles of Safety and Performance of Medical Devices and method used to demonstrate conformity)

| **Essential Principle** | **Applicable to the devices?** | **Method of conformity** | **Identify of specific documents** |
| --- | --- | --- | --- |
| **General Requirements** |  |  |
| 1. Medical devices shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with the use of the medical device for its intended purpose constitute acceptable risks when weighed against the intended benefits to the patient and are compatible with a high level of protection of health and safety. (มีความปลอดภัยและความเสี่ยงจากการใช้งานต้องได้รับการยอมรับเมื่อถ่วงน้ำหนักกับประโยชน์ที่จะได้) | Yes | Horizontal standards: ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) ISO 10993-1:2009 corr.:2010 (Biological evaluation of medical devices - Pt 1 - Evaluation and testing within risk management) and its relatedISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ISO 11607-2:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 2 - Validation requirements for the processes)ISO 11137-1:2006 **(Sterilization of health care products - Radiation - Pt 1: Requirements for development, validation and routine control of a sterilization process for medical devices**)ISO 11137-2:2013 (Sterilization of health care products - Radiation -- Pt 2: Establishing the sterilization dose)ISO 14971:2007 (Application of risk management to medical devices)MEDDEV 2.7.1:2016 (A guide for clinical evaluation)Vertical standards: ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices)ISO 15142-1:2003 (Metal Intramedullary nailing systems – Pt 1: Intramedullary nails)ISO 15142-2:2003 (Metal Intramedullary nailing systems – Pt 2: Locking components)ISO 15142-3:2003 (Metal Intramedullary nailing systems – Pt 3: Connection devices and reamer diameter measurements)  | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxxBiological test report No. xxx-xxx-xxx Packaging validation report No. xxx-xxx-xxxSterilization validation report No. xxx-xxx-xxx Risk management report No. xxx-xxx-xxx Clinical evaluation report No. xxx-xxx-xxxProduct verification test report No. xxx-xxx-xxx |
| 2. The solutions adopted by the product owner for the design and manufacture of the medical devices shall conform to safety principles, taking account of the generally acknowledged state of the art. In selecting an appropriate solution for the design and manufacture of a medical device so as to minimize any risks associated with the use of the medical device, the product owner shall apply the following principles: * Identify any hazard and associated risk arising from the use of the medical device for its intended purpose, and any foreseeable misuse of the medical device, (การควบคุมความเสี่ยงมีได้ 3 แนวทาง)
* eliminate or reduce risks as far as reasonably practicable through inherently safe design and manufacture,
* If appropriate, ensure that adequate protective measures are taken, including alarms if necessary, in relation to any risk that cannot be eliminated, and
* Inform users of any residual risks.
 | Yes | Horizontal standards: ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005)  ISO 14971:2007 (Application of risk management to medical devices)ISO 10993-1:2009 corr.:2010 (Biological evaluation of medical devices - Pt 1 - Evaluation and testing within risk management) and its relatedISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ISO 11607-2:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 2 - Validation requirements for the processes)ISO 11137-1:2006 **(Sterilization of health care products - Radiation - Pt 1: Requirements for development, validation and routine control of a sterilization process for medical devices**)ISO 11137-2:2013 (Sterilization of health care products - Radiation -- Pt 2: Establishing the sterilization dose)EN 1041:2008 (Information supplied by the manufacterer)ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied – Pt1: General requirements)Vertical standards: ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices)ISO 15142-1:2003 (Metal Intramedullary nailing systems – Pt 1: Intramedullary nails)ISO 15142-2:2003 (Metal Intramedullary nailing systems – Pt 2: Locking components)ISO 15142-3:2003 (Metal Intramedullary nailing systems – Pt 3: Connection devices and reamer diameter measurements) | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Risk management report No. xxx-xxx-xxx Biological test report No. xxx-xxx-xxx Packaging validation report No. xxx-xxx-xxxSterilization validation report No. xxx-xxx-xxx Instruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxxProduct verification test report No. xxx-xxx-xxx |
| 3. Medical devices shall achieve the performance intended by the product owner and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device. (บรรลุสมรรถนะตามวัตถุประสงค์ที่ระบุ) | Yes | Horizontal standards:ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) MEDDEV 2.7.1:2016 (A guide for clinical evaluation)ISO 10993-1:2009 corr.:2010 (Biological evaluation of medical devices - Pt 1 - Evaluation and testing within risk management) and its relatedISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ISO 11607-2:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 2 - Validation requirements for the processes) SO 11137-1:2006 **(Sterilization of health care products - Radiation - Pt 1: Requirements for development, validation and routine control of a sterilization process for medical devices**)ISO 11137-2:2013 (Sterilization of health care products - Radiation -- Pt 2: Establishing the sterilization dose)Vertical standards: ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices)ISO 15142-1:2003 (Metal Intramedullary nailing systems – Pt 1: Intramedullary nails)ISO 15142-2:2003 (Metal Intramedullary nailing systems – Pt 2: Locking components)ISO 15142-3:2003 (Metal Intramedullary nailing systems – Pt 3: Connection devices and reamer diameter measurements) | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Clinical evaluation report No. xxx-xxx-xxxBiological test report No. xxx-xxx-xxx Packaging validation report No. xxx-xxx-xxxSterilization validation report No. xxx-xxx-xxx Product verification test report No. xxx-xxx-xxx |
| 4. The characteristics and performances referred to in Clauses 1, 2 and 3 shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the medical device, as indicated by the product owner, when the medical device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained and calibrated, if appropriate, in accordance with the product owner’s instructions. (ลักษณะและสมรรถนะต้องคงอยู่ตลอดอายุเครื่องมือแพทย์) | Yes | Horizontal standards: ASTM F1980:2016 (Accelerated Aging of Sterile Medical Device Packages)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) EN 1041:2008 (Information supplied by the manufacterer)ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied – Pt1: General requirements)Vertical standards: ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices) | Accelerated test report (package and product) No. xxx-xxx-xxxInstruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxx |
| 5. The medical devices shall be designed, manufactured and packed in such a way that their characteristics and performances, when it is being used for its intended purpose, will not be adversely affected during its transport and storage, if the transport and storage is carried out in accordance with the instructions and information provided by the product owner. (ลักษณะและสมรรถนะต้องคงอยู่หลังการขนส่งและการจัดเก็บ) | Yes | Horizontal standards: ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) ASTM D4169:2016 (Testing of Shipping Containers and Systems), table 1 ASTM D5276:2009 (Drop test of loaded containers)ASTM D999:2008 (Vibration testing)ASTM D642:2015 (Determining Compressive resistance)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems)EN 1041:2008 (Information supplied by the manufacterer)ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied – Pt1: General requirements)Vertical standards: -  | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Transport and storage test report No. xxx-xxx-xxxInstruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxx |
| 6. The benefits must be determined to outweigh any undesirable side effects for the performances intended. (ถ่วงน้ำหนักระหว่างประโยชน์กับผลข้างเคียงอันไม่พึงประสงค์) | Yes | Horizontal standards: ISO 14971:2007 (Application of risk management to medical devices)MEDDEV 2.7.1:2016 (A guide for clinical evaluation)Vertical standards: - | Risk management report No. xxx-xxx-xxx Clinical evaluation report No. xxx-xxx-xxx |
| 7. Medical devices shall require clinical evidence, appropriate for the use and classification of the medical device, demonstrating that the medical device complies with the applicable provisions of the essential principles. A clinical evaluation shall be conducted. (ทำการประเมินด้านคลินิก)  | Yes | Horizontal standards: MEDDEV 2.7.1:2016 (A guide for clinical evaluation)Vertical standards: - | Clinical evaluation report No. xxx-xxx-xxx |
| **Design and Manufacturing Requirements**  |  |  |
| 8. Chemical, physical and biological properties |  |  |
| 8.1 The medical devices shall be designed and manufactured in such a way as to ensure the characteristics and performance requirements referred to in Clauses 1 to 6 of the ‘General Requirements’ are met. Particular attention shall be paid to: (ต้องพิจารณาเลือกวัสดุที่ใช้)* The choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
* The chemical and physical properties of the material used,
* The compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the medical device,
* The choice of materials used shall reflect, where appropriate, matters such as hardness, wear and fatigue strength.
 | Yes | Horizontal standards:ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) ASTM F136 - 13 Standard Specification for Wrought Ti-6AL-4V ELI Alloy for Surgical Implant ApplicationsISO 10993-1:2009 corr.:2010 (Biological evaluation of medical devices - Pt 1 - Evaluation and testing within risk management) and its relatedISO 10993-3:2014 (Biological evaluation - Pt 3 - Tests for genotoxicity)ISO 10993-5:2009 (Biological evaluation - Pt 5 - Tests for in vitro cytotoxicity)ISO 10993-6:2016 (Biological evaluation - Pt 6 - Tests for local effect after implantation)ISO 10993-10:2010 (Biological evaluation - Pt 10 - Tests for irritation) ISO 10993-10:2010 (Biological evaluation - Pt 10 - Tests for sensitization) ISO 10993-11:2017 (Biological evaluation - Pt 11 - Tests for acute systemic)ISO 10993-11:2017 (Biological evaluation - Pt 11 - Tests for subchronic systemic)Vertical standards: - | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Material specification No. xxxxxx Safety material data sheet No. xxxxxxBiological test report No. xxx-xxx-xxx  |
| 8.2 The medical devices shall be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the medical devices and to patients, taking account of the intended purpose of the product. In minimizing risks, particular consideration shall be given to the duration and frequency of any tissue exposure associated with the transport, storage or use of the medical device. (ลดความเสี่ยงที่จะมีสารส่งผลถึงบุคลากรที่อยู่ในการขนส่ง การจัดเก็บ และการใช้) | Yes | Horizontal standards: ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) ASTM D4169:2016 (Testing of Shipping Containers and Systems), table 1 ASTM D5276:2009 (Drop test of loaded containers)ASTM D999:2008 (Vibration testing)ASTM D642:2015 (Determining Compressive resistance)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ISO 11607-2:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 2 - Validation requirements for the processes)Vertical standards: - | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Transport and storage test report No. xxx-xxx-xxxPackaging validation report No. xxx-xxx-xxx |
| 8.3 The medical devices shall be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the medical devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these medicinal products and that the performance of the medicinal product is maintained in accordance with the intended purpose of the medicinal product. (มีความปลอดภัยจากการใช้เมื่อมีการสัมผัสกับสารต่างๆ และสารยา ระหว่างการใช้งาน) | No (The device has no medicinal product used with) | - | - |
| 8.4 Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in the relevant legislation that applies and which is liable to act upon the body with action ancillary to that of the medical device, the safety, quality and performance of the medical device as a whole shall be verified, as well as the safety, quality and efficacy of the incorporated substance in relation to the intended purpose of the medical device. For the purposes of this paragraph, “medicinal product” includes any stable derivative of human blood or human plasma. (กรณีที่มีสารยาร่วมหรือเป็นสารยาเอง ต้องมีข้อมูลความปลอดภัย คุณภาพ และสมรรถนะการใช้งาน) | No (The device has no medicinal product incorporated) | - | - |
| 8.5 The medical devices shall be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the medical device. (ลดความเสี่ยงของสารที่จะรั่วออกมา) | Yes (วัสดุที่ใช้ผลิต) | Horizontal standards:ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) ASTM F136 - 13 Standard Specification for Wrought Ti-6AL-4V ELI Alloy for Surgical Implant ApplicationsISO 10993-1:2009 corr.:2010 (Biological evaluation of medical devices - Pt 1 - Evaluation and testing within risk management) and its relatedVertical standards:- | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Material specification No. xxxxxx Safety material data sheet No. xxxxxxBiological test report No. xxx-xxx-xxx  |
| 8.6 Medical devices shall be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the medical device taking into account the nature of the environment in which the medical device is intended to be used. (ลดความเสี่ยงของสารที่จะซึมเข้าหรือออกโดยไม่ตั้งใจในสภาพแวดล้อมที่มีการใช้งาน) | Yes (Moisture ingress) | Horizontal standards:ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ISO 11607-2:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 2 - Validation requirements for the processes)Vertical standards:- | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Packaging validation report No. xxx-xxx-xxx |
| 9. Infection and microbial contamination  |  |  |
| 9.1 The medical devices and manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to any persons. (ความเสี่ยงจากการติดเชื้อ) The design shall: * Allow easy handling, and, where necessary:
* Reduce as far as reasonably practicable and appropriate any microbial leakage from the medical device and/or microbial exposure during use,
* If appropriate, minimizes contamination of the medical device, or specimen where applicable, by the patient, user or other person, or contamination of the patient by the medical device, during its use.
 | Yes | Horizontal standards:ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ISO 11607-2:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 2 - Validation requirements for the processes) ISO 11137-1:2006 **(Sterilization of health care products - Radiation - Pt 1: Requirements for development, validation and routine control of a sterilization process for medical devices**)ISO 11137-2:2013 (Sterilization of health care products - Radiation -- Pt 2: Establishing the sterilization dose)ISO 11737-2:2009 (Sterilization of medical devices - Pt 2 -Test of sterility of a sterilization process), sterility testVertical standards:- | Packaging validation report No. xxx-xxx-xxxSterilization validation report No. xxx-xxx-xxx  |
| 9.2 Where a medical device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device. | No (The device has no biological origin applied) | - | - |
| 9.3 Products incorporating non-viable tissues, cells and substances of animal origin falling within the definition of a medical device, shall originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended purpose of the tissues. The product owner is required to retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.  | No (The device has no part of animal origin applied) | - | - |
| 9.4 For products incorporating cells, tissues and derivatives of microbial or recombinant origin falling within the definition of a medical device, the selection of sources/donors, the processing, preservation, testing and handling of cells, tissues and derivatives of such origin shall be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.  | No (The device has no microbial or recombinant origin applied) | - | - |
| 9.5 For products incorporating non-viable human tissues, cells and substances falling within the definition of an IVD medical device, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.  | No (The device has no human tissues, cells and substance of IVD applied) | - | - |
| 9.6 Medical devices labeled as having a special microbiological state shall be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the product owner.  | No (The device has no special microbiological state) | - | - |
| 9.7 Medical devices delivered in a sterile state shall be designed, manufactured and packed to ensure that they remain sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the product owner. (ส่งมอบแบบฆ่าเชื้อ ต้องคงสภาวะปราศจากเชื้อภายใต้การขนส่ง การจัดเก็บ) | Yes | Horizontal standards: ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005) ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ISO 11607-2:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 2 - Validation requirements for the processes)SO 11137-1:2006 **(Sterilization of health care products - Radiation - Pt 1: Requirements for development, validation and routine control of a sterilization process for medical devices**)ISO 11137-2:2013 (Sterilization of health care products - Radiation -- Pt 2: Establishing the sterilization dose)ISO 11737-2:2009 (Sterilization of medical devices - Pt 2 -Test of sterility of a sterilization process), sterility testASTM D4169:2016 (Testing of Shipping Containers and Systems), table 1 ASTM D5276:2009 (Drop test of loaded containers)ASTM D999:2008 (Vibration testing)ASTM D642:2015 (Determining Compressive resistance)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems)Vertical standards: -  | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxxPackaging validation report No. xxx-xxx-xxxSterilization validation report No. xxx-xxx-xxxTransport and storage test report No. xxx-xxx-xxx |
| 9.8 Medical devices labeled either as sterile or as having a special microbiological state shall have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods. (ฉลากต้องระบุวิธีการฆ่าเชื้อและการฆ่าเชื้อต้องมีการทดสอบกระบวนการฆ่าเชื้อ) | Yes | Horizontal standards:EN 1041:2008 (Information supplied by the manufacterer)ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied – Pt1: General requirements)SO 11137-1:2006 **(Sterilization of health care products - Radiation - Pt 1: Requirements for development, validation and routine control of a sterilization process for medical devices**)ISO 11137-2:2013 (Sterilization of health care products - Radiation -- Pt 2: Establishing the sterilization dose)ISO 11737-2:2009 (Sterilization of medical devices - Pt 2 -Test of sterility of a sterilization process), sterility testVertical standards: -  | Instruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxxSterilization validation report No. xxx-xxx-xxx  |
| 9.9 Medical devices intended to be sterilized shall be manufactured in appropriately controlled (e.g. environmental) conditions. (กรณีมีการฆ่าเชื้อ สภาวะแวดล้อมการผลิตต้องมีการควบคุม) | Yes | Horizontal standards:ISO 14644-1: 2015 (Cleanrooms and associated controlled environments - Pt 1 - Classification of air cleanliness), ISO 14644-2: 2015 (Cleanrooms and associated controlled environments - Pt 2 - Monitoring of cleanroom performance) and ISO 14644-3: 2005 (Cleanrooms and associated controlled environments - Pt 3 - Test methods) ISO 11737-1:2006 (Sterilization of medical devices - Pt 1 - Determination of microorganisms), bioburden testISO 14698-1:2003 (Cleanrooms and associated controlledenvironments - Bio-contamination - Pt 1: General principlesVertical standards: - | Cleanroom validation report No. xxx-xxx-xxxMicrobiological test report No. xxx-xxx-xxx |
| 9.10 Packaging systems for non-sterile medical devices shall keep the product at the level of cleanliness stipulated and, if the medical devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilization indicated by the product owner. The medical device shall be produced in appropriately controlled conditions. (กรณีไม่มีการฆ่าเชื้อ สภาวะการผลิตต้องมีการควบคุม) | No(The device is provided sterile only) | - | - |
| 9.11 The packaging and/or label of the medical device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition. (ต้องทำบรรจุภัณฑ์/ฉลากที่แยกให้ออกระหว่างฆ่าเชื้อและไม่ได้ฆ่าเชื้อ) | No(The device is provided sterile only) | - | - |
| 10. Manufacturing and environmental properties  |  |  |
| 10.1 If the medical device is intended for use in combination with other medical devices or equipment, the whole combination, including the connection system shall be safe and shall not impair the specified performance of the medical devices, or equipment with which it is used. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. (กรณีที่ต้องใช้ร่วมกับเครื่องมือแพทย์อื่นๆ ตรงจุดใช้ร่วมต้องมีความปลอดภัย ข้อจำกัดตรงจุดใช้ร่วมต้องมีการระบุ)  | Yes(การ combine กับชุดเครื่องมือผ่าตัดสำหรับระบบแกนโลหะใส่ในโพรงกระดูก) | Horizontal standards: EN 1041:2008 (Information supplied by the manufacterer)ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied – Pt1: General requirements)Vertical standards: - | Instruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxx |
| 10.2 Medical devices shall be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: (ความเสี่ยงเหล่านี้ต้องได้รับการควบคุม) | Yes | Horizontal standards: ISO 13485:2016 (Medical devices - Quality management systems – Requirements for regulatory purposes)Thai FDA GMP:2548 (2005)  ISO 14971:2007 (Application of risk management to medical devices)Vertical standards: - | ISO 13485:2016 Certificate No. xx xx xx xxxxx xxxGMP: 2548 Certificates No. x-x-xx-xx-xx-xxxxx Risk management report No. xxx-xxx-xxx  |
| * The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; (ความเสี่ยงต่อการบาดเจ็บตรงจุดเชื่อมต่อที่เป็นด้านกายภาพ)
 | Yes (การ connect กันของระบบแกนโลหะใส่ในโพรงกระดูก) | ISO 15142-1:2003 (Metal Intramedullary nailing systems – Pt 1: Intramedullary nails)ISO 15142-2:2003 (Metal Intramedullary nailing systems – Pt 2: Locking components)ISO 15142-3:2003 (Metal Intramedullary nailing systems – Pt 3: Connection devices and reamer diameter measurements) | Product verification test report No. xxx-xxx-xxx  |
| * Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; (ความเสี่ยงจากสภาพแวดล้อมที่มีผลกระทบ เช่น สนามแม่เหล็ก, ความดัน, ความชื้น, อุณหภูมิ)
 | Yes(สนามแม่เหล็ก)Yes(ความชื้น อุณหภูมิ) | EN 1041:2008 (Information supplied by the manufacterer)ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied – Pt1: GeneralASTM F1980:2016 (Accelerated Aging of Sterile Medical Device Packages)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems)ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices)ISO 15142-1:2003 (Metal Intramedullary nailing systems – Pt 1: Intramedullary nails)ISO 15142-2:2003 (Metal Intramedullary nailing systems – Pt 2: Locking components)ISO 15142-3:2003 (Metal Intramedullary nailing systems – Pt 3: Connection devices and reamer diameter measurements) | Instruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxxAccelerated test report (package and product) No. xxx-xxx-xxx |
| * The risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; (ความเสี่ยงเมื่อมีการสัมผัสกับสารต่างๆ ระหว่างการใช้งาน)
 | Yes สารคัดหลั่ง | ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices)  | Product verification test report No. xxx-xxx-xxx |
| * The risks of accidental penetration of substances into the medical device; (ความเสี่ยงของสารที่ล่วงล้ำเข้าไปเข้าในเครื่องมือแพทย์โดยอุบัติเหตุ)
 | Yes (ปริมาณรังสีที่จะล่วงล้ำไปทำปฏิกริยากับวัสดุ) | ISO 11137-1:2006 **(Sterilization of health care products - Radiation - Pt 1: Requirements for development, validation and routine control of a sterilization process for medical devices**)ISO 11137-2:2013 (Sterilization of health care products - Radiation -- Pt 2: Establishing the sterilization dose)ASTM F1980:2016 (Accelerated Aging of Sterile Medical Device Packages)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems) ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices) | Accelerated test report (package and product) No. xxx-xxx-xxx |
| * The risk of incorrect identification of specimens; (ความเสี่ยงจากการบ่งชี้ตัวอย่างผิด)
 | No(The device is a non IVD) | - | - |
| * The risks of reciprocal interference with other medical devices normally used in the investigations or for the treatment given; (ความเสี่ยงจากการรบกวนซึ่งกันและกันเมื่อใช้ร่วมกับเครื่องมือแพทย์อื่นๆ)
 | No(The device is a non active) | - | - |
| * Risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. (ความเสี่ยงจากการซ่อมบำรุงหรือสอบเทียบทำไม่ได้, จากการเสื่อมสภาพของวัสดุหรือกลไกการควบคุม)
 | Yes(จากการเสื่อมสภาพของวัสดุ) | ASTM F1980:2016 (Accelerated Aging of Sterile Medical Device Packages)ISO 11607-1:2006, amen.:2014 (Packaging for terminally sterilized medical devices - Pt 1 - Requirements for packaging systems)ASTM F1264:2016 (Test Methods for Intramedullary Fixation Devices) | Accelerated test report (package and product) No. xxx-xxx-xxx |
| 10.3 Medical devices shall be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to medical devices whose intended purpose includes exposure to or use in association with flammable substances or substances which could cause combustion. (ลดความเสี่ยงของไฟไหม้หรือการระเบิด) | No(The device is a non active) | - | - |
| 10.4 Medical devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances. (ของเสียต้องมีการจัดการทิ้งที่ปลอดภัย) | Yes (เมื่อมีการนำออกจากจุดที่เคยอยู่) | Horizontal standards:EN 1041:2008 (Information supplied by the manufacterer)ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied – Pt1: General requirements)Vertical standards:- | Instruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxx |
| 11. Medical devices with a diagnostic or measuring function  |  |  |
| 11.1 Medical devices with a measuring function shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the medical device. The limits of accuracy, precision and stability shall be indicated by the product owner. (กำหนดความเที่ยงตรง ความแม่นยำ ความเสถียร ของค่าที่วัด) | No (The device has no these functions | - | - |
| 11.2 Medical devices shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. In particular, the design shall address the sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate. (ระบุความไวในการให้ผล ค่าที่เจาะจง ค่าจริง ค่าที่ให้ผลหมือนเดิม) | No (The device has no these functions) | - | - |
| 11.3 Where the performance of medical devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials shall be assured through a quality management system. (กรณีที่สมรรถนะการวัดค่าขึ้นอยู่กับเครื่องคำนวณหรือวัสดุควบคุม การสอบกลับของค่าที่วัดได้ต้องมั่นใจว่าถูกต้องผ่านระบบการจัดการคุณภาพ) | No (The device has no these functions) | - | - |
| 11.4 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking into account of the intended purpose of the medical device. (สเกลของการวัดค่าต้องใช้หลัก ergonomic) | No (The device has no these functions) | - | - |
| 11.5 Wherever possible values expressed numerically shall be in commonly accepted, standardized units, and understood by the users of the medical device. (ค่าที่วัดได้ต้องเป็นหน่วยมาตรฐาน) | No (The device has no these functions) | - | - |
| 12. Protection against radiation (for active medical device) |  |  |
| 12.1 General Medical devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. (รังสีที่แผ่ต้องให้น้อย แต่ยังคงใช้งานได้ตามวัตถุประสงค์การใช้งาน) | No (The device has no such source) | - | - |
| 12.2 Intended radiation  |  |  |
| 12.2.1 Where medical devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it shall be possible for the user to control the emissions. Such medical devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. (ประโยชน์จากรังสีที่ตั้งใจให้แผ่ ถ่วงน้ำหนักกับความเสี่ยงจากรังสีที่แผ่) | No (The device has no such source) | - | - |
| 12.2.2 Where medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall be fitted, where practicable, with visual displays and/or audible warnings of such emissions. (รังสีที่ตั้งใจให้แผ่ ต้องแสดงให้รู้ด้วยการเห็นหรือได้ยิน) | No (The device has no such source) | - | - |
| 12.3 Unintended radiation Medical devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate. (รังสีที่ไม่ตั้งใจให้แผ่ต้องให้มีการลด) | No (The device has no such source) | - | - |
| 12.4 Instructions for use The operating instructions for medical devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. (คำแนะนำการใช้งานให้ระบุ วิธีการป้องกัน การใช้ผิดวิธี ความเสี่ยงจากการติดตั้งผิด) | No (The device has no such source) | - | - |
| 12.5 Ionizing radiation  |  |  |  |
| 12.5.1 Medical devices intended to emit ionizing radiation shall be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended purpose. (รังสีมีประจุที่แผ่สามารถปรับ ควบคุม ให้ได้ตามวัตถุประสงค์การใช้งาน) | No (The device has no such source) | - | - |
| 12.5.2 Medical devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. (รังสีมีประจุที่แผ่เพื่อวัตถุประสงค์การวินิจฉัย ปริมาณรังสีต้องแผ่โดนคนไข้และผู้ใช้งานน้อยที่สุด)  | No (The device has no such source) | - | - |
| 12.5.3 Medical devices emitting ionizing radiation intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam. (รังสีมีประจุที่แผ่เพื่อวัตถุประสงค์การรักษา ปริมาณรังสีที่ให้ต้องวัดและควบคุมได้) | No (The device has no such source) | - | - |
| 13. Requirements for medical devices connected to or equipped with an energy source (for active medical device) |  |
| 13.1 Medical devices incorporating electronic programmable systems, including software, shall be designed to ensure the repeatability, reliability and performance of these systems according to the intended purpose. In the event of a single fault condition in the system, appropriate means shall be adopted to eliminate or reduce as far as practicable and appropriate consequent risks. (กรณีที่มี software สมรรถนะการใช้งานต้องเป็นไปตามวัตถุประสงค์การใช้งาน) | No (The device is a non active, no energy source) | - | - |
| 13.2 For medical devices which incorporate software or which are medical software in themselves, the software shall be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. (กรณีที่มี software ตัว software ต้องได้รับการ validate) | No (The device is a non active, no energy source) | - | - |
| 13.3 Medical devices where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply. (กรณีที่มาจากแหล่งจ่ายไฟภายใน ต้องมีอุปกรณ์ที่ระบุสถานะของแหล่งจ่ายไฟ) | No (The device is a non active, no energy source) | - | - |
| 13.4 Medical devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure. (กรณีที่มาจากแหล่งจ่ายไฟภายนอก ต้องมีระบบสัญญาณเตือนว่าแหล่งจ่ายไฟมีปัญหา) | No (The device is a non active, no energy source) | - | - |
| 13.5 Medical devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. (กรณีที่มีวัตถุประสงค์ในการเฝ้าติดตามสัญญาณชีพ ต้องมีอุปกรณ์เตือนผู้ใช้งาน) | No (The device is a non active, no energy source) | - | - |
| 13.6 Medical devices shall be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other medical devices or equipment in the vicinity where the medical device is located. (ความเสี่ยงจากการเกิดแม่เหล็กไฟฟ้าที่รบกวนการทำงานซึ่งกันและกัน) | No (The device is a non active, no energy source) | - | - |
| 13.7 Medical devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended. (ให้มีภูมิต่อแม่เหล็กไฟฟ้าที่รบกวนเพื่อให้สามารถทำงานได้ตามวัตถุประสงค์การใช้งาน) | No (The device is a non active, no energy source) | - | - |
| 13.8 Protection against electrical risks A medical device shall be designed and manufactured in a way that ensures that, as far as possible, a patient, or any other person is protected against the risk of accidental electric shock when it is installed and maintained as indicated by the product owner, is being used under normal conditions of use and in the event of a single fault condition. (ความเสี่ยงจากไฟฟ้าช็อต) | No (The device is a non active, no energy source) | - | - |
| 14. Protection against mechanical risks (for active medical device) |  |  |
| 14.1 Medical devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks associated with the use of the medical device. (ความเสี่ยงเชิงกล) | No (The device is a non active, no mech. risks | - | - |
| 14.2 Medical devices shall be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the medical devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. (ความเสี่ยงที่เกิดจากการสั่นของตัวเครื่อง) | No (The device is a non active, no mech. risks | - | - |
| 14.3 Medical devices shall be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. (ความเสี่ยงที่เกิดเสียงที่แผ่) | No (The device is a non active, no mech. risks | - | - |
| 14.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle shall be designed and constructed in such a way as to minimize all possible risks. (ความเสี่ยงที่จุดเชื่อมต่อกับแหล่งพลังงาน) | No (The device is a non active, no mech. risks | - | - |
| 14.5 Accessible parts of the medical devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal use. (ความเสี่ยงจากความร้อน) | No (The device is a non active, no mech. risks | - | - |
| 15. Protection against the risks posed to the patient by supplied energy or substances (for active medical device) |  |
| 15.1 Medical devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the delivered rate and/or amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user. (กรณีที่มีวัตถุประสงค์การให้พลังงานหรือสาร อัตราการให้ต้องตั้งได้และคงไว้ด้วยความถูกต้อง) | No (The device is a non active, no energy source) | - | - |
| 15.2 Medical devices shall be fitted with the means of preventing and/or indicating any inadequacies in the delivered rate and/or amount which could pose a danger. Medical devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source. (กรณีที่มีวัตถุประสงค์ข้างต้น ให้มีวิธีป้องกันไม่ให้อยู่ในระดับที่เป็นอันตราย) | No (The device is a non active, no energy source) | - | - |
| 15.3 The function of the controls and indicators shall be clearly specified on the medical devices. Where a medical device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient. (วิธีการควบคุมและการแสดงค่าต้องชัดเจน) | No (The device is a non active, no energy source) | - | - |
| 16. Active implantable medical devices  |  |  |
| 16.1 An active implantable medical device shall incorporate, display, emit or exhibit a code or unique characteristic that can be used to identify: (ต้องมีการแสดงรหัสหรือลักษณะเฉพาะที่ระบุ)* The type of medical device;
* The product owner of the medical device; and
* The year of manufacture of the medical device.
 | No (The device is a non active device) | - | - |
| 16.2 The identifier shall be readable without the need for surgery to the person in whom the medical device is implanted. (การระบุต้องทำได้โดยต้องไม่ทำการผ่าตัด) | No (The device is a non active device) | - | - |
| 17. Protection against the risks posed to the patient for medical devices for self-testing or self-administration  |  |
| 17.1 Such medical devices shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user’s technique and environment. The information and instructions provided by the product owner shall be easy for the user to understand and apply. (การใช้งานขึ้นกับความชำนาญและวิธีการของผู้ใช้ ผลที่ได้สามารถแตกต่างได้ขึ้นกับเทคนิคและสภาวะแวดล้อมของผู้ใช้) | No (The device is not a self-testing or self-administration device) | - | - |
| 17.2 Such medical devices shall be designed and manufactured in such a way as to reduce as far as practicable the risk of error in the handling of the medical device and, if applicable, the specimen, and also in the interpretation of results. (ความเสี่ยงจากความผิดพลาดในการจัดการ และการตีความ) | No (The device is not a self-testing or self-administration device) | - | - |
| 17.3 Such medical devices shall, where reasonably possible, include a procedure by which the user can verify that, at the time of use, the medical device will perform as intended by the product owner. (มีวิธีปฏิบัติที่ผู้ใช้งานสามารถทวนสอบได้ ณ เวลาใช้งาน) | No (The device is not a self-testing or self-administration device) | - | - |
| 18. Information supplied by the product owner The following information shall be provided with a medical device, having regard to the training and knowledge of potential users of the medical device: (จัดหาข้อมูลที่มีเนื้อหา)* information identifying the medical device;
* information identifying the product owner of the medical device;
* information explaining how to use the medical device safely
 | Yes | Horizontal standards:EN 1041:2008 (Information supplied by the manufacterer)EN 980:2008 (Symbols for use in the labelling of medical devices)Vertical standards:- | Instruction for use No. xxx-xxx-xxxLabel No. xxx-xxx-xxx |
| 19. Clinical Investigation Clinical investigations on human subjects shall be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. Clinical investigations on human subjects shall be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. (การทดสอบทางคลินิกในมนุษย์ให้ดำเนินการตามปฏิญญาเฮลซิงกิ ให้ดำเนินการทุกขั้นตอน ตั้งแต่การพิจารณาความต้องการ การตัดสินผลการศึกษา จนถึงการตีพิมพ์ผลงาน) | Yes | Horizontal standards:ISO 14155:2011 (Clinical investigation of medical devices for human subjects - Good clinical practice)MEDDEV 2.7.1:2016 (A guide for clinical evaluation)Vertical standards:- | Clinical evaluation report No. xxx-xxx-xxx  |