Comparison between the STED of GHTF and the Technical Document of KFDA

April, 2011

Contents of the STED

Reference documents

- **Global Harmonization Task Force**

  http://www.ghtf.org

- **GHTF/SG1/N011:2008**

  Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

Contents of the STED

1. Device Description and Product Specification, Including Variants and Accessories

1) Device Description

- a general description including its intended use/purpose;
- the intended patient population and medical condition to be diagnosed and/or treated and other considerations such as patient selection criteria;
- principles of operation;
- risk class and the applicable classification rule according to *Principles of Medical Devices Classification;*
- an explanation of any novel features;
- a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it;

Contents of the STED

1. Device Description and Product Specification, Including Variants and Accessories (Continued)

- a description or complete list of the various configurations/variants of the device that will be made available;
- a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this will include: labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.
- a description of the materials incorporated into key functional elements and those making either direct contact with a human body or indirect contact with the body, e.g., during extracorporial circulation of body fluids.

Contents of the STED

1. Device Description and Product Specification, Including Variants and Accessories (Continued)

2) Product Specification

The STED should contain a list of the features, dimensions and performance attributes of the medical device, its variants and accessories (if such are within the scope of the STED), that would typically appear in the product specification made available to the end user, e.g. in brochures, catalogues and the like.

3) Reference to similar and previous generations of the device

Where relevant to demonstrating conformity to the Essential Principles, and to the provision of general background information, the STED should contain an overview of:

the manufacturer's previous generation(s) of the device, if such exist; and/or similar devices available on the local and international markets.

Contents of the STED

2. Labelling

Information on labelling should include the following:

- labels on the device and its packaging;
- instructions for use; and
- promotional material.

3. Design and Manufacturing Information

1) Device Design
2) Manufacturing Processes
3) Design and Manufacturing Sites

4. Essential Principles (EP) Checklist

5. Risk Analysis and Control Summary

Contents of the STED

6. Product Verification and Validation

As a general rule, the STED should summarize the results of verification and validation studies undertaken to demonstrate conformity of the device with the Essential Principles that apply to it. Such information would typically cover:

1) engineering tests;
2) laboratory tests;
3) simulated use testing;
4) any animal tests for demonstrating feasibility or proof of concept of the finished device;
5) any published literature regarding the device or substantially similar devices.

Contents of the STED

6. Product Verification and Validation (Continued)

In addition, where applicable to the device, the STED should contain detailed information on:

1) biocompatibility;
2) medicinal substances incorporated into the device, including compatibility of the device with the medicinal substance;
3) biological safety of devices incorporating animal or human cells, tissues or their derivatives;
4) sterilization;
5) software verification and validation;
6) animal studies that provide direct evidence of safety and performance of the device, especially when no clinical investigation of the device was conducted;
7) clinical evidence.

Contents of Technical Document

Reference documents

- **Regulations for Reviewing Technical Document, etc. of Medical Device**
  KFDA Notification No.2010-42
  (Amended on June 11, 2010)

- **Regulations for Product Classification of Medical Device and Class by Product**
  KFDA Notification No. 2010-91
  (Amended on December 21, 2010)

- **KFDA Medical Device Homepage**
  (http://md.kfda.go.kr)

Article 1
(Purpose)

The purpose of these Regulations is to specify details necessary for review of technical documents, etc. for Medical Devices as provided in Paragraph 7 of Article 6 of the “Medical Device Act” and Paragraph 5 of Article 5 and Paragraph 4 of Article 7 of the “Enforcement Regulations of the Medical Device Act”.

Article 2
(Definition)

The definitions of the terms

Article 3
(Subject of Review, Etc.)

1. The subject of review of data regarding technical documents shall be Medical Devices for which product manufacture or product import license (including amended license) is intended to be obtained.

2. For Medical Devices falling under one of the followings from among the Medical Devices of the above Paragraph 1, Data regarding safety and efficacy shall be included in the review:
   1) Medical Devices falling under New Structure;
   2) Medical Devices falling under New Performance;
   3) Medical Devices falling under New Purpose of Use;
   4) Newly Developed Medical Devices;
   5) Medical Devices having a serious influence on the safety and efficacy of the product, whose "Major Technical Characteristics" mentioned in Attached Table 1 are wholly or partially different from the Medical Devices that have already been licensed (approved) or notified (also including change); and
   6) Medical Devices for which the license conditions are changed from export to domestic sale, to the extent that such Medical Devices fall under Items 1 through 5 above.

[Attached Table 1]
Major Technical Characteristics by Groups by type of Medical Devices

Group by type	Major Technical Characteristics
Non-electric Medical Devices	Purpose of use, principle of action, form, performance
Electric Medical Devices	Purpose of use, principle of action, form, available energy source(or transmission), performance
Medical Devices for Radiation Technicians	
Light-generating Medical Devices	
Medical Supplies	Purpose of use, form, raw material, performance
Dental Materials	

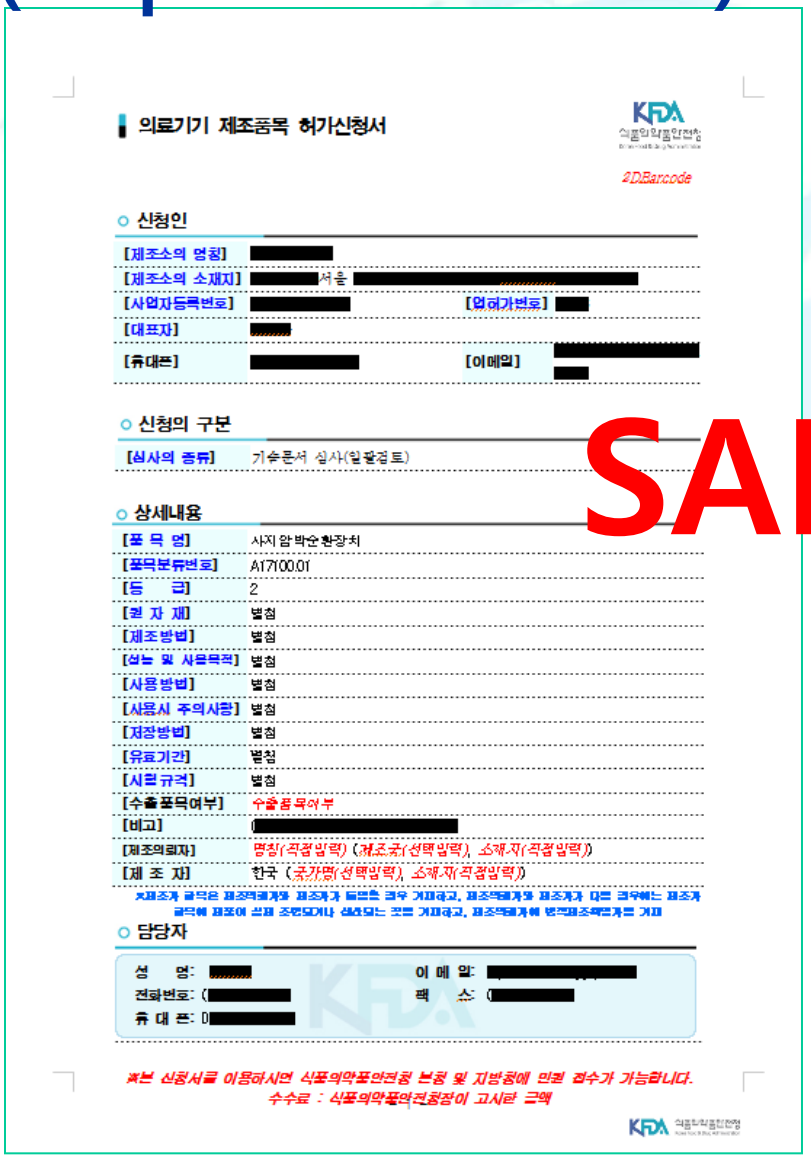
Article 4
(Scope of Review)

When the KFDA Commissioner received a Request for Review of technical documents, etc. for a Medical Device as provided in Paragraph 2 of Article 7 of the "Enforcement Regulations of the Medical Device Act", a separate review shall be conducted with respect to each manufacturer (importer) of the product and each product item (model) thereof, in principle, and any product added after a Request for Review is received shall be excluded from review; provided, however, that the Same Product Group can be reviewed with one technical document.

Article 6
(Application for Review of Technical Documents, Etc.)

The party who desires to have technical documents, etc. reviewed for a Medical Device under Article 7 of the Enforcement Regulations shall submit, to the Commissioner, a copy of the Request for Review as per Attached **Form No. 7** of the Enforcement Regulations, and attached materials, etc. specified in Paragraph 2 of Article 7 of the Enforcement Regulations, together with electronic recording media (e.g. CD, diskette, etc.) made using a dedicated program as specified by the Commissioner.

Form No. 7
(Request for Review)



의료기기 제조품목 허가신청서

2DBarcode

○ 신청인

[제조소의 명칭] [redacted]
[제조소의 소재지] [redacted]서울 [redacted]
[사업자등록번호] [redacted] [업허가번호] [redacted]
[대표자] [redacted]
[휴대폰] [redacted] [이메일] [redacted]

○ 신청의 구분

[심사의 종류] 기술문서 심사(일괄점토)

○ 상세내용

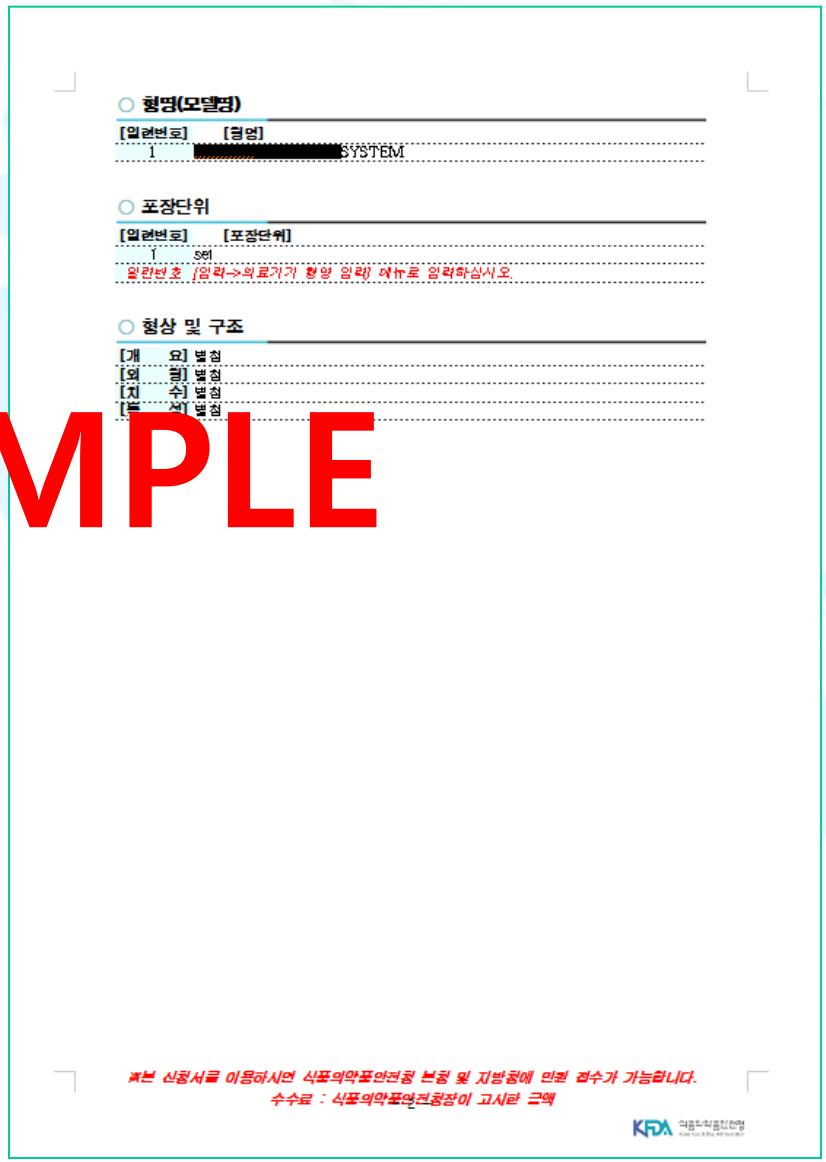
[품 목 명] 사지 압박순환장치
[품목분류번호] A17100.01
[등 급] 2
[원 자 재] 별첨
[제조방법] 별첨
[성능 및 사용목적] 별첨
[사용방법] 별첨
[사용시 주의사항] 별첨
[저장방법] 별첨
[유효기간] 별첨
[시험규격] 별첨
[수출품목여부] 수출품목여부
[비고] [redacted]
[제조의뢰자] 명칭(직접입력) (제조국(선택입력), 소재지(직접입력))
[제 조 자] 한국 (국가명(선택입력), 소재지(직접입력))

*제조자 글목은 제조의뢰자와 제조자가 동일은 경우 기재하고, 제조의뢰자와 제조자가 다른 경우에는 제조자 글목에 제조에 실제 조한도이나 생산하는 곳을 기재하고, 제조의뢰자에 한국제조의뢰자를 기재

○ 담당자

성 명: [redacted] 이 메 일: [redacted]
전화번호: ([redacted]) 팩 스: ([redacted])
휴 대 폰: 0[redacted]

*본 신청서를 이용하시면 식품의약품안전청 본청 및 지방청에 민원 접수가 가능합니다.
수수료 : 식품의약품안전청장이 고시한 금액



○ 형명(모델명)

[일련번호] [형명]
1 [redacted]SYSTEM

○ 포장단위

[일련번호] [포장단위]
1 set

일련번호 (입력->의료기기 형일 입력) 메뉴로 입력하십시오

○ 형상 및 구조

[개 요] 별첨
[외 형] 별첨
[치 수] 별첨
[기 타] 별첨

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수수료 : 식품의약품안전청장이 고시한 금액

Article 7
(Requirements for Attached Data)

1. Data regarding review of technical documents

A. Data regarding purpose of use

Data regarding principle of action, indications, efficacy and effectiveness, purpose of use, etc. of the product

B. Data regarding physiochemical properties

1) Physiochemical properties of the part of the Medical Device which is to contact the human body or to be put into the human body, or to contact blood, fluid or drug, etc. injected into the human body
2) In the case of Medical Devices using dental materials or polymer materials, etc., data regarding physiochemical properties and safety including the chemical structure of the raw materials, infrared absorption, UV absorption, atomic absorption, melting point, boiling point, durability, hardness, color, elute, surface properties, etc. and
3) In the case of a Medical Device whose end product contains animal-derived ingredients or animal-derived ingredients are used during production, data regarding animal name, country of origin, age, part of use, process, ingredient name, etc.

Article 7
(Requirements for Attached Data)

C. Data regarding electromechanical safety

1) In the case of electrically-driven Medical Devices, data regarding test items, test method, test conditions, reference values, test results, test facilities, test manager, etc. as provided in the "Common Standards and Specifications for Electromechanical Safety of Medical Devices"(KFDA Notification) and separately established standards and specifications for each item, or equivalent or higher international standards (IEC, ISO, etc.)

2) In the case of products equipped with software or software for independent use, data including model or name, version, algorithm or structure, major function and function display, operating environment, etc. of the software.

Article 7
(Requirements for Attached Data)

D. Data regarding biological safety

In the case of a Medical Device or its component(s), which is to contact the human body or to be put into the body, or to contact blood, fluid or drug, etc. injected into the human body, data regarding test items, test method, test conditions, reference values, test results, test facilities, test manager, etc. as provided in the "Common Standards and Specifications for Electromechanical Safety of Medical Devices" (KFDA Notification) and separately established standards and specifications for each item, or equivalent or higher international standards (IEC, ISO, etc.); provided that in the case of Medical Devices using raw materials with biological safety as notified by the Commissioner, it is not required to submit biological safety related data, as long as (i) the analysis certificate, etc. proving that the raw materials have been used, (ii) a raw material supply certificate, and (iii) manufacturing process-related data proving that simple mechanical processing has been done are attached.

Article 7
(Requirements for Attached Data)

E. Data regarding radiation safety

In the case of Medical Device using radiation or its Components requiring radiation safety of the Medical Device such as exposure to radiation, etc., data regarding test items, test method, test conditions, reference values, test results, test facilities, test manager, etc., as tests conducted under international standards (IEC, etc.) related with radiation safety

F. Data regarding electromagnetic interference (EMI)

In the case of the Medical Device requiring safety against EMI or its Components, data regarding tests (including those additionally conducted for Medical Devices under international standards by separate items) as provided in the "Common Standards and Specifications for Electromagnetic Safety of Medical Devices" (KFDA Notification), or equivalent or higher international standards (IEC, etc.)

Article 7
(Requirements for Attached Data)

G. Data regarding performance

Data regarding tests including preclinical performance test such as function intended by the product, performance, shelf life(available period), sterilization, animal experiment, etc.

H. One of the following data for Test Specification for confirmation of performance and safety of the product and the grounds for establishment, and actual measurement values

1) Domestic and foreign standards(KS, IEC, ISO, ASTM, etc.) necessary for validation of performance or safety, which is intended by the product; provided that if there is no specification, test specification and test method specified by the manufacturer, and the supporting data thereof
2) Data regarding actual measurement values including the content mentioned in Attached Table 3
3) Test Specification applied to the product for which the country of production and manufacturing site are the same, the raw material is the same as that of the product which has already been licensed (approved), and its performance is also identical, and the supporting data thereof

[Attached Table 3]
Matters Required To Be Included In Data Regarding Actual Measurement Values

1) Name and address of the laboratory
2) Company that requested testing, its representative and address
3) Serial number and numbers of each page and the whole page of test report
4) Name and indication of test product
5) Date when a request for the test is submitted, or test date
6) Date of issue of test report
7) Signature or seal of a person who is responsible for test report
8) Test standard and test method; provided that if no specification is established, the grounds for establishment
9) Result of testing
10) Matters regarding collection of the product subject to test and the method of test thereof (if additional pretreatment is necessary for testing)
11) Data on the testing system, quantity of experimental animals, their gender, system, species, age, etc. (in case of tests using animals, cells, and microorganisms)
12) Environmental factors of testing that may influence the test results

Article 7
(Requirements for Attached Data)

2. Data regarding safety and efficacy review

A. Data regarding origin or grounds for discovery and development

Data which can demonstrate scientific appropriateness of the principle, use method, manufacturing method, etc. used to develop the product

B. Data regarding stability

1) Data regarding overview, storage method, setting of shelf life, etc., as test result of stability or durability (including matters of sequential changes in the sterilized material for a sterilized Medical Device)
2) Data regarding test conditions, measurement items, and preservation period on each test(long-term testing, accelerated test, stress test, etc.), as well as of test method, test result, etc.

Article 7
(Requirements for Attached Data)

C. Data regarding results of clinical trial

Data regarding testing for human beings in order to demonstrate safety and efficacy of the Medical Devices used for clinical trial; except that for items of Class 1 or 2, clinical data may instead be submitted.

1) Generals

Data regarding clinical trial record for the Medical Device, issued by the director of the clinical trial institution approved by the Commissioner which conducted the clinical trial in accordance with the clinical trial plan approved by the Commissioner provided that such data shall include the followings:

A) Purpose of the clinical trial
B) Institution and its address
C) Name and position of manager, supervisor, investigators, and co-investigators
D) Test requestor and its address
E) Product name of the Medical Device subject to clinical trial, and the manufacturing number, form, performance, specification, etc. thereof
F) Subject Diseases and indications
G) Period of the clinical trial

Article 7
(Requirements for Attached Data)

H) Method of the clinical trial
  (1) Inclusion/exclusion criteria for subjects, the target number of subjects
  (2) Operational method or instructions for use, and the grounds for establishment
  (3) If the Medical Device for comparative testing is used, the reason for selection
  (4) Combination therapy
  (5) Observational items, measurement items, laboratory items, measurement criteria, and test method
  (6) Performance evaluation criteria, evaluation method, and interpretation method (statistics)
  (7) Safety evaluation criteria including side effects and test method

I) Record of the clinical trial (The expected number of clinical cases, the actual number of subjects, the number of completed cases, the number of dropouts, and the reason shall be mentioned, and in this case, side effects by subjects, etc. shall be included.)

J) Summary of case report

K) Other data necessary for confirmation of clinical trial record

Article 7
(Requirements for Attached Data)

2) The number of cases for the clinical trial

Data demonstrating that the number of cases for the clinical trial is decided in a statistically proper manner in comprehensive consideration of the characteristics of the Medical Device, clinical trial method, etc., such data being produced at two or more clinical trial institutions per indication, in principle; provided, however, that if it is difficult to actually secure the number of cases for the clinical trial due to few cases of the disease symptoms occurring , data capable of proving this shall be additionally attached.

3) Evaluation of effective ratio

(A) Data demonstrating that the effective ratio of the Medical Device against the disease symptom has clinically statistical significance based on medical principles; if it is deemed appropriate, it can be recognized.

(B) If deemed necessary by the Commissioner for evaluation of effective ratio, a request for review may be made to the Medical Device Committee.

Article 7
(Requirements for Attached Data)

D. Data regarding current status of foreign uses, etc.

Data regarding sale or licenses (approvals) in foreign countries, side effects reported at use, grounds for product manufacture license, etc., and if not used in the country of production, the reason therefore

E. Data regarding comparative examination with domestic and foreign similar products and characteristics of the Medical Device

Data regarding comparative examination with similar Medical Devices on structure, principle, purpose of use, use method, etc., as well as of performance and characteristics unique to the Medical Device differentiated from other existing Medical Devices

Article 7
(Requirements for Attached Data)

Documentary evidence shall fall under one of the followings

1. **Test data issued by the testing laboratory registered in the KFDA;**

2. **Test data issued by the National Certification Body(NCB) under the IECEE CB-Scheme, which is run by the International Electro technical Commission(IEC);**

3. **Good Laboratory Practice(GLP) test data issued by an authorized GLP laboratory under GLP of the Organization for the Economic Cooperation and Development(OECD);**

4. **Data appearing in journals, which are registered in the Science Citation Index;**

Article 7
(Requirements for Attached Data)

Documentary evidence shall fall under one of the followings

5. Data, which is issued by the director of the special agency and is deemed appropriate through examination of the content (including overview of testing facilities, major equipment, research personnel of the agency, investigator's experience, etc.) as tested at domestic and foreign special agencies including colleges or research institutes, etc.; provided that unless there is internally or externally authorized test specification, data regarding safety and performance test on design and development of the product, which was performed under the manufacturer's quality management system; and
6. Data (such as clinical trial results, etc.) submitted and evaluated as of the time of the license (approval) being obtained in the country where the Medical Device was developed, which data shall demonstrate that such data was received or approved by the government of such country or the registration authorities to which license (approval) affairs are delegated by such government.

Article 9
(Preparation of a Request for Review)

1. A Request for Review under the Attached **Form 7** of the Enforcement Regulations shall be prepared .

2. If some of the attached data set forth in Article 7 above is unnecessary in vi ew of the characteristics of the product, the reason therefore shall be menti oned in detail.

3. **For foreign data, in principle, a Korean abstract containing a summary of major contents, and the original, shall be attached, and the whole translation of such data shall be required to be attached only to the extent necessary.**

Article 10
(Product Name)

1. For **product name**, if matters specified in the Regulations on Classifications of Medical Devices and Classes by product classifications as designated by the Commissioner are satisfied, **the classification name, classification code, and class** shall be described provided, however, that if the item name does not satisfy the Regulations on Items of Medical Devices and Class by Product, the Request for Review shall be filled in based on the result of examination as provided in Paragraph 5 of Article 3 of Regulations for Approval, etc. of Medical Device;

2. For **model name**, the model name of the product subject to review shall be mentioned; and

3. For a **Combined Medical Device or a Complex Medical Device**, the Request for Review shall be filled out for each of the component Medical Devices thereof in compliance with the provisions of the above Articles 1 and 2, based on the main purpose of use and superior grades of each of such component Medical Devices thereof.

Product Classification

Regulations for Product Classification of Medical Device and Class by Product
KFDA Notification No. 2010-91
(Amended on December 21, 2010)

의료기기 품목 및 품목별 등급에 관한 규정

제정 2005. 3. 23 식품의약품안전청 고시 제2005-17호
개정 2005.12. 6 식품의약품안전청 고시 제2005-71호
개정 2006. 9. 28 식품의약품안전청 고시 제2006-44호
개정 2009. 1. 6 식품의약품안전청 고시 제2009- 2호
개정 2009. 6. 30 식품의약품안전청 고시 제2009-41호
개정 2010.12. 21 식품의약품안전청 고시 제2010-91호

제1조(목적) 이 규정은 「의료기기법」 제3조 및 같은 법 시행규칙 제2조에 따른 의료기기의 품목 및 품목별 등급에 관하여 필요한 사항을 정함을 목적으로 한다.

제2조(품목 분류 기준) ① 의료기기의 성능을 발휘하고 사용 목적을 달성함을 주된 기능으로 하는 독립적으로 제조·판매되는 의료기기 부분품으로서 안전성·유효성 확보가 필요한 경우 별도의 의료기기 품목으로 분류할 수 있다.
②의료기기를 둘 이상 조합하여 별도의 의료기기로 사용하는 경우 그 전체를 하나의 의료기기로 분류할 수 있다.

A37000 레이저 진료기 Laser apparatus for medical use

A37010.01 레이저수술기 [3] Laser, surgical 매질로서 탄산가스를 이용하는 레이저 수술기

A37010.02 색소레이저수술기 [3] Laser, surgical, dye 매질로서 유기화합물(색소, Dye)을 이용하는 레이저 수술기

A37010.03 아르곤레이저수술기 [3] Laser, surgical, argon 매질로서 아르곤을 이용하는 레이저 수술기

A37010.04 엔디야그레이저수술기 [3] Laser, surgical, Nd:YAG 매질로서 엔디야그를 이용하는 레이저 수술기

A37010.05 크립톤레이저수술기 [3] Laser surgical unit, krypton 매질로서 크립톤을 이용하는 레이저 수술기

A37010.06 루비레이저수술기 [3] Laser, surgical, ruby 매질로서 루비를 이용하는 레이저 수술기

A37010.07 구리증기레이저수술기 [3] Laser, surgical, copper vapor 매질로서 구리증기를 이용하는 레이저 수술기

A37010.08 알렉산드라이트레이저수술기 [3] Laser surgical unit, alexandrite 매질로서 알렉산드라트레이를 이용하는 레이저 수술기

A37010.09 홀륨야그레이저수술기 [3] Laser, surgical, holmium:YAG 매질로서 홀륨야그를 이용하는 레이저 수술기

A37010.10 반도체레이저수술기 [3] Laser surgical unit, diode 매질로서 반도체를 이용하는 레이저 수술기

A37010.11 기타레이저수술기 [3] Laser surgical unit, others 상기 이외의 매질을 사용하는 레이저 수술기

A37020.01 의료용레이저조사기 [3] Laser, therapeutic 통증 완화 등을 목적으로 방사되는 광에너지(레이저)를 피부에 쬐어 사용하는 기구.

A37020.01 [3] Laser, therapeutic A device used to expose light energy(laser) onto the skin, which is radiated for the purpose of pain relieving

Article 11
(Appearance, Structure and Dimensions)

1. Appearance, structure, weight, dimensions, etc. shall be mentioned including the summary of the product (if the product is of liquid or powder type, the external feature shall be mentioned), and a clear- color picture shall be attached, which can identify the whole product and its Components; provided that the summary of the product shall include, among others, the principle applied for the development of the product.

2. For electromechanically-driven Medical Devices, the followings shall be mentioned:
   A. Appearance, structure, weight, dimensions, and function of each part;
   B. Principle of operation;
   C. Electric rating;
   D. Form and degree of protection against electric shock
   E. Apparatus for Safety
   F. Block diagram; and
   G. Circuit diagram (power supply, mounting, etc.) or isolation diagram of the insulation, which can demonstrate electromechanical safety
   H. Structure or algorithm, and major function of the equipped software, with the exception of equipped software, which is not used for diagnosis, measurement, and analysis

Article 11
(Appearance, Structure and Dimensions)

다. 제품의 구성 및 특성

> ✍ 제품을 구성하고 있는 주요 부분품들에 대한 설명과 제품을 이해할 수 있도록 작동원리 등을 아래의 예와 같이 작성하십시오

예

1) 구성 및 작동원리

○ 본 기기는 본체와 배터리 삽입부 그리고 운반 케이스로 구성되어있다.

○ 작동원리 : GaAlAs의 반도체(매질)에 DC 3V의 전원을 인가, 누름핀을 통하여 파장이 635~670 nm의 적외선레이저를 발생

2) 전기적 정격

○ DC 3V, 50 mAh

3) 전기충격에 대한 보호형식 및 정도

○ 내부전원기기 BF형

4) 안전장치 : 의뢰한 제품의 안전장치 기재(FUSE 등)

5) 계통도

○ 스위치 on → DC 3V → ① 반도체 매질 → ② 레이저 발생

① : 버튼 스위치를 누르면 GaAlAs의 반도체(매질)에 DC 3V의 전원이 인가된다.

② 반도체 메질에서 파장이 635~670 nm의 적외선레이저를 발생

6) IEC에 의한 레이저 등급 : 3A

Article 12
(Raw Material or Ingredient and Quantity)

1. Mentions for medical instruments or dental materials, etc.

Serial No.	Name	Raw Material or Ingredient and Quantity	Standard	Remarks (Contact to the human body and the contact part)

2. Mentions for electrically or mechanically-driven devices, etc.

Serial No.	Component	Component Control No. or Raw Material	Standard	Quantity	Remarks

Article 12
(Raw Material or Ingredient and Quantity)

원자재

「1. 사지압박순환장치

번호	부분품명	관리번호	원자재	규격	수량	비고
1	본체	DS-001	알루미늄	240(W)×180(D)×100mm(H)	1	
2	표시판	DS-002	아크릴	240(W)× 2(D)×78mm(H)	1	
3	자동/수동 버튼	DS-003	ABS 수지	-	1	
4	시작/정지 버튼	DS-004	ABS 수지	-	1	
5	에어 호스	DS-005	폴리에틸렌	-	1	
6	하단 케이스	DS-006	ABS 수지	240(W)× 2(D)×78mm(H)	1	
7	상단 케이스	DS-007		240(W)× 2(D)×78mm(H)	1	
8	배터리 커버	DS-008	ABS 수지	111.6mm(W) × 32.6mm(D)	1	
9	커프	DS-009	폴리에스테르	6종류 에어커프(치수참조)	6	
10	솔레노이드	DS-010	-	DC24V, Normal Open	1	
11	에어펌프	DS-011	-	12V(DC12V, 0.4A)	1	
12	PCB	DS-012	-	1.2T	1	
13	아답터	DS-013	-	DC18V, 4A (SMPS), 5.5㎜X2.5㎜ jack	1	
14	배터리	DS-014	리튬이온	3.7V 리튬이온 × 6개	1	
15	내장소프트웨어	DS-015	Doctus-SW-V1.0	version 1.0		

Article 13
(Manufacturing Method)

The phrase 'The manufacturing method of the manufacturer is followed' shall be described provided, however, that upon one of the followings, the relevant matter shall be additionally described :

1. In the case of manufacturing method of sterilized Medical Devices, sterilizing method, sterilizing conditions, packing method, etc. and

2. In the case of a Medical Device whose end product contains animal-derived ingredients or uses animal-derived ingredients during production, data regarding animal name, country of origin, age, part of use, process, ingredient name, etc.

Article 14
(Performance and Purpose of Use)

Performance and purpose of use shall be mentioned as follows:

1. In the case of performance, functional characteristics and specification (performance) of the product shall be mentioned;

2. The purpose of use shall be mentioned based on documentary evidence of the disease symptoms, efficacy and effectiveness, or purpose of use which is intended by the manufacturer and

3. In the case of a Combined Medical Device, the Request for Review shall describe the performance and purpose of use as set forth in the above Items 1 and 2 for both each of the component Medical Devices thereof and such Combined Medical Device. In the case of a Composite Medical Device, the Request for Review shall describe, for each of the component Medical Devices thereof, the performance and purpose of use as set forth in the above Items 1 and 2.

Article 14
(Performance and Purpose of Use)

5. 성능 및 사용목적

> ✍ 의료용레이저조사기의 기능적 특성과 규격(성능) 및 사용목적을 아래의 예와 같이 작성하십시오

예

가. 성능

1) Unit Class : Low-level laser class 1A
2) Laser GaALAs(Gallium-Aluminium-Arsenide) Diode, Continuos beam
3) Power output : max 6㎽
4) Laser wavelength: 635-670㎚
5) 전원 : 2 x 1.5 알카라인 배터리(micro: AAA/IEC Type LR03)
6) 정격전압 : 3V DC
7) Operating mode : Continuous operation
8) 전격에 대한 보호형식 및 정도 : 내부전원 BF형 기기

나. 사용목적

; 방사되는 광에너지(레이저)를 피부에 조사하여 통증완화에 사용

Article 15
(Operation Method or Instruction for Use)

For operation method or use method, the Request for Review shall describe preparations before use, operation method, use method, keeping and control method after use. Specifically, if sterilization prior to use is required, the sterilizing conditions and method shall be exactly mentioned, and if software is embedded in the Medical Device or is independently used, the Request for Review shall accurately describe the method of using such function, together with a screen picture showing each function of the program.

Article 16
(Packing Unit)

For the packing unit of the Medical Device, the Request for Review shall describe the minimum unit easy to handle, and shall mention 'Internal Packing Unit' in the case of manufacturing and 'Manufacturer's Packing Unit' in the case of imports.

Article 17
(Precautions for Use)

1. Indication of warning and age, gender, and physical condition for use in consideration of characteristics of the Medical Device;
2. Precautions for use by specialist's prescription, fatal side effects caused by careless use, and cautions against accident;
3. Relevant cautions if necessary for prevention of negligent accident.

Article 18
(Storage Method or Shelf Life)

1. For Medical Devices requiring control of specific storage or sterilization, etc. to maintain the quality of the product, the Request for Review shall describe storage method (storage conditions, etc.), so that safety can be secured.
2. If a shelf life(valid term) is specified, the Request for Review shall be completed based on the data verified under Sub-item B, Item 2, Paragraph 1, Article 7, or other recognized documentary evidence.

Operation Method or Instruction for Use

ITC ASIA

6. 조작방법 또는 사용방법

의료용레이저조사기에 대한 조작방법 또는 사용방법을 다음 사항을 포함하여 아래의 예와 같이 작성하십시오.

가. 사용전의 준비사항
나. 조작방법 또는 사용방법
다. 사용후 보관 및 관리방법
라. 사용상의 주의사항

예

가. 사용전의 준비사항

의료용레이저조사기에 대한 사용전의 준비사항은 제[illegible]사용하는데 필요한 준비사항을 아래의 예와 같이 작성하십시오

(1) 사용 전에 사용설명서를 충분히 숙지할 것
(2) 사용설명서에서 지시한 1.5V AAA 배터리 2개를 배터리 삽입부에 삽입한다.
(3) 전원스위치를 눌러서 레이저 빔이 출력되는지 확인한다.

나. 조작방법 또는 사용방법

의료용레이저조사기에 대한 제품의 정상적인 사용을 위하여 사용자가 취하여야 할 일련의 작동순서를 차례대로 아래의 예와 같이 상세히 작성하십시오

(1) 통증이 있는 부위에 조사기를 1cm 이격시킨다.
(2) on/off 버튼을 눌러 조사기를 작동시킨다.
(3) 조사기를 15분에서 30분간 조사한다. 이때 피부에 직접 닿지 않도록 한다.

다. 사용후 보관 및 관리방법

의료용레이저조사기에 대한 제품의 사용후 제품(부분품 포함)의 보관 및 관리를 위해 필요한 조건 또는 방법을 아래의 예와 같이 작성하십시오.

(1) 기기를 장시간 사용하지 않을 시에는 배터리를 기기와 분리하여 보관할 것
(2) 청소: 기기를 사용한 후에는 아이소피릴 알콜로 레이저 헤드 부분을 닦는다. 알콜로 천을 적신 후 닦는다. 레이저 헤드 부분을 알콜에 담그지는 말 것
(3) 재사용 전에 기기를 완전히 말린 후 사용할 것

[illegible]. 사용상의 주의사[illegible]

의료용레이저조사기에 대한 사용할 때 주의사항은 경고의 표시, 사용대상 연령·성별 등에 대한 주의사항, 전문의의 처방에 따른 사용상의 주의사항 및 사용상의 부주의에 따른 치명적인 부작용·사고발생 등에 대한 주의사항 등 의료기기의 특성에 고려하여 기재하고, 안전사고의 예방에 필요한 사항이 있는 경우에는 이를 아래의 예와 같이 작성하시기 바랍니다.

(1) 레이저 빔을 직접 응시하지 말 것
(2) 어린이나 상처를 받기 쉬운 곳에는 사용치 말 것
(3) 박피술(Face Lift) 등을 받은 사람은 피부미용전문가나 피부과 의사의 상담을 받은 후에 사용할 것
(4) 레이저 빔이 직접 다른 사람에게 조사되어서는 안 된다.
(5) 어린이의 손이 닿지 않는 곳에 보관 할 것
(6) 마취가스나 가연성 물질과 같이 사용하지 말 것
(7) 장기간 사용하지 않을 경우는 배터리를 분리 시켜 놓을 것.

Article 19
(Test Specification)

1. Based on the attachment specified in Article 7 herein, necessary test items shall be selected among the test items for Medical Devices as mentioned in Attached Table 2 according to the characteristics of the product, and relevant test standard and test method shall be mentioned;

2. If the 「Medical Device Standard Specification」(KFDA Notification) or equivalent or higher international standards (IEC．SO, etc.) are applied as Test Specification, the Request for Review shall describe the title, number and year of issue of the standards. The same is required when such specification or standards are applied partially.

3. The test standard shall clearly mention the permissible range of reference values, based on which acceptance/rejection of the test result is determined, and if the test result is influenced by surrounding conditions such as temperature, humidity, etc., the conditions shall be specified

4. The test method shall be mentioned in a specific and summarized manner so that the test result can be exactly calculated according to the sequence;

5. In the case of a Combined Medical Device or a Composite Medical Device, the Test Specification to be applied for the evaluation of the Combined Medical Device as a whole or the Composite Medical Device as a whole shall be established separately from the Test Specification to be applied for the evaluation of each of the component Medical Devices thereof.

[Attached Table 2]
Test Items for Medical Devices

1. Conditions of preparation for test solution

If test specifications on physiochemical properties and biological safety are established to secure safety of the Medical Device, conditions of preparation of test solution shall be established.

2. Tests on physiochemical properties

The Test Specification of physiochemical properties, such as chemical structure test, shall be established for a Medical Device or its component(s) which is to contact the human body or to be inserted into the human body, or to contact blood, fluid or drug, etc. injected into the human body.

3. Tests on electromechanical safety

The Test Specification required for validation of electromechanical safety of the electrically-driven Medical Device shall be established based on the data specified in Sub-item C, Item 1, Paragraph 1, Article 7 herein.

4. Tests on biological safety

The Test Specification required for validation of safety of a Medical Device which is to contact the human body or to be inserted into the human body, or to contact blood, fluid or drug, etc. injected into the human body, shall be established based on the data specified in Sub-item D, Item 1, Paragraph 1, Article 7 herein.

[Attached Table 2]
Test Items for Medical Devices

5. Tests on radiation safety

For Medical Devices using radiation, the Test Specification on radiation safety related to the structure shall be established based on the data specified in Sub-item E, Item 1, Paragraph 1, Article 7 herein.

6. Tests on Electro Magnetic Interference (EMI)

In case of Medical Devices requiring tests on EMI (electromagnetic interference, electromagnetic susceptibility), the Test Specification of EMI shall be established based on the data specified in Sub-item F, Item 1, Paragraph 1, Article 7 herein.

7. Tests on performance

The Test Specification necessary for validation of function, performance and quality of the Medical Device shall be established.

8. Other tests necessary for safety and efficacy validation

The Test Specification necessary for validation of sterilization and sterilized residual gas shall be established according to characteristics of the Medical Device.

Article 19
(Test Specification)

ITC ASIA

시험규격

1. 전기,기계적 안전성에 관한 시험

"의료기기 전기, 기계적 안전에 관한 공통기준 규격 (식품의약품안전청고시 2009-137호)에 따른다.

2. 전자파 장해에 관한 시험

[redacted]는 "비-생명 유지 기기"에 해당함.

(1) 전자파간섭(장해)에 관한 시험

번호	시험항목	시험기준	시험방법
1	전자파전도 (단자장해전압) 시험 (※내부전원기기의 경우, 면제)	식품의약품안전청 고시 제2007-32호 1종 B급기기로서 별표 1의 5.1 단자 장해전압의 허용기준을 만족한다.	식품의약품안전청 고시 제 호 별표 1의 [illegible]에 따라 시험한다.
2	전자파방사 시험	식품의약품안전청 고시 제2007-32호 1종 B급기기로서 별표 1의 5.2 전자파방사장해의 허용기준을 만족한다.	식품의약품안전청 고시 제 2007-32호 별표 1의 전자파장해(간섭)에 따라 시험한다.

(2) 전자파내성에 관한 시험

번호	시험항목	시험기준	시험방법
1	정전기방전(ESD) 시험	식품의약품안전청 고시 2007- 32호 별표2 36,202 내성의 부합판정기준을 따른다.	식품의약품안전청 고시 2007 -32호 별표2 36,202.2정전기방전(ESD)에 따라 시험한다
2	방사성 RF 전자기장 시험	식품의약품안전청 고시 2007- 32호 별표2 36,202 내성의 부합판정기준을 따른다.	식품의약품안전청 고시 2007-32호 별표2 36,202.3 방사성 RF전자기장 에 따라 시험한다.

3. 성능에 관한 시험

(1) 공통부분

번호	시험항목	시험기준	시험방법
1	외관	제품을 구성하는 외장 부품에는 사용상에 유해한 상처, 오염, 변형, 녹이 없어야 함	육안 또는 손으로 만져보면서 확인한다.
2	타이머 시험	각 모드별 동작시간이 설정된 값(1~15분) ± 10% 이내일 것.	타이머를 이용하여 시험기준에 적합한가를 확인한다.
3	Complete 알람	작동시간이 종료되면 알람이 울릴 것 (D mode 와 E mode에서는 동작하며, 혈압측정 모드는 제외)	기기를 동작시켜 확인한다.
4	전[illegible]	① [illegible]생 시 차단할 수 있는 2.5A [illegible]가 기기 내에 설치되어있을 것. ② [illegible]작동 중에 디스플레이 작동버튼의 ON/[illegible]를 누르면 모든 출력이 정지될 것. (긴[illegible]지 버튼의 역할)	기기를 동작시켜 확인한다.
5	입력전원 변동시험	220Vac±10%의 입력전원으로 가동하였을 때 이상 없이 동작할 것	전압조정기로 입력전원을 변동시켜 확인한다.

Article 20 (Labeling)

Matters that are required to be mentioned in the container, packing, and attached document of each Medical Device shall be as provided in Articles 19 through 23 of the Act and Articles 26 through 28 of the Enforcement Regulations, and regarding matters of technical information including characteristics of the Medical Device as specified in Item 10, Paragraph 1, Article 27 of the Enforcement Regulations, only the details specified in Article 19 herein shall be mentioned; provided, however, that in the case of a Combined Medical Device or a Complex Medical Device, such matters shall be mentioned for each of the component Medical Devices thereof.

Article 20 (Labeling)

ITC ASIA

의료기기 기술문서 기재사항

1.제품명, 형명(모델명)		1)제품명: 사지압박순환장치 2)형명(모델명): [redacted]
2.제조업자의 상호의 주소		1)상호 : [redacted] 2)주소 : [redacted]
3.제조원 (제조국, 제조회사명)		1)제조국 : 대한민국 2)제조회사명 : (주)[redacted]
4.품목허가번호 및 사용목적		1)품목허가번호 : 허가 후 기재 2)사용목적 : 허가 후 기재
5.제조번호와 제조년월일		제조 시 기재
6.중량 또는 포장단위		1)중량 : 4.5 Kg 2)포장단위 : 1SET
7.사용방법 및 사용상 주의사항		사용설명서 참조
8.보관 또는 저장방법		사용설명서 참조
9.기타 필요한 사항	1)정격전원의 주파수, 정격전압	AC 220 V, 60 Hz / DC 16 V, 3.75A
	2)소비전력	72VA
	3)전기충격에 대한 보호형식 및 보호정도	내부전원형기기 및 2급기기, BF형 기기
	4)소프트웨어	명칭 : [redacted] 버전 : Ver. 1.0
10. 본제품은 "의료기기" 임		

Thank you.

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