

2. 의료기기법 시행령

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
<p>제1조(목적) 이 영은 의료기기법에서 위임된 사항과 그 시행에 관하여 필요한 사항을 규정함을 목적으로 한다.</p>	<p>Article 1 (Purpose) The purpose of this Decree is to stipulate the matters delegated by the Medical Device Act and the matters necessary for the implementation of the Medical Device Act.</p>
<p>제2조(의료기기위원회의 구성) ①의료기기법(이하 “법”이라 한다) 제5조제1항의 규정에 의한 의료기기위원회(이하 “위원회”라 한다)는 위원장 1인과 부위원장 2인을 포함한 50인 이상 100인 이하의 위원으로 구성한다.</p>	<p>Article 2 (Constitution of the Medical Device Committee) ① The Medical Device Committee (hereinafter referred to as the “Committee”) under Paragraph 1 of Article 5 of the Medical Device Act (hereinafter referred to as the “Act”) shall consist of fifty (50) or more but up to one hundred (100) members including one (1) chairperson and two (2) deputy chairpersons.</p>
<p>②위원장은 보건복지부차관이 되고, 부위원장중 1인은 식품의약품안전청차장이 되며, 다른 1인은 위원중에서 호선한다. <개정 2008.2.29,2010.3.15></p>	<p>② The Deputy Minister of Health and Welfare shall become the chairperson of the Committee, and the Deputy Commissioner of the Korea Food and Drug Administration shall become one (1) of the two deputy chairpersons of the Committee. The remaining deputy chairperson shall be appointed among the members of the Committee. < Amended on February 29, 2008 and March 15, 2010, respectively></p>
<p>③위원회의 위원은 다음 각호의 1에 해당하는 자 중에서 보건복지부장관이 임명 또는 위촉한다. <개정 2006.6.12,2008.2.29,2010.3.15></p> <ol style="list-style-type: none"> 1. 의료기기 관련 업무를 담당하는 4급 이상의 공무원 또는 고위공무원단에 속하는 일반직공무원 2. 의료기기 관련 단체, 시민단체(비영리민간단체지원법 제2조의 규정에 의한 비영리민간단체를 말한다), 관련 학회 및 대학의 장이 추천한 자 3. 의료기기에 관한 학식과 경험이 풍부한 자 	<p>③ The Minister of Health and Welfare shall appoint or invite the members of the Committee among the persons who fall under any of the following Items: <Amended on June 12, 2006, February 29, 2008, and March 15, 2010, respectively></p> <ol style="list-style-type: none"> 1. Government officials of Grade 4 or higher or government officials of general position belonging to senior civil service who are involved in the duties related to medical devices; 2. Persons recommended by organizations related to medical devices, civic groups (non-profit private organizations falling under Article 2 of the Non-profit Private Organization Support Act), or the heads of relevant academic societies or colleges; or 3. Persons who have extensive knowledge and experience in medical devices.

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<p>제3조(위원의 임기) 위원회의 임기는 2년으로 한다. 다만, 공무원인 위원회의 임기는 해당직에 재직하는 기간으로 한다.</p>	<p>Article 3 (Term of the Committee members) The Committee member's term shall be two years. The term of a Committee member for government official, however, shall be limited to the period of time during which the member is the incumbent of the relevant position.</p>
<p>제4조(위원장의 직무) ①위원장은 위원회를 대표하며, 위원회의 업무를 통할한다.</p>	<p>Article 4 (Responsibilities of the Chairperson) ① The Chairperson shall represent the Committee and oversee the operation of the Committee.</p>
<p>②위원장이 부득이한 사유로 직무를 수행할 수 없는 때에는 위원장이 지명한 부위원장이 그 직무를 대행한다.</p>	<p>② If the Chairperson becomes unable to perform duties for unavoidable reasons, a vice-chairperson designated by the Chairperson shall take his or her place as the Chairperson.</p>
<p>제5조(회의) ①위원장은 위원회를 소집하고, 그 의장이 된다.</p>	<p>Article 5 (Meetings) ① The Chairperson shall convene a Committee meeting and becomes the chairperson of the meeting.</p>
<p>②위원장은 보건복지부장관·식품의약품안전청장 또는 재적위원 과반수의 회의소집의 요구가 있는 때에는 지체없이 회의를 소집하여야 한다. <개정 2008.2.29,2010.3.15></p>	<p>② The Chairperson shall convene a meeting of Committee members without delay upon receipt of a meeting request from the Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration (hereinafter referred to as the “KFDA Commissioner”), or more than one-half (1/2) of the incumbent Committee members. <Amended on February 29, 2008 and March 15, 2010, respectively></p>
<p>③위원회의 회의는 재적위원 과반수의 출석과 출석위원 과반수의 찬성으로 의결한다.</p>	<p>③ In a Committee meeting, the Committee shall make a decision by the affirmative vote of more than one-half (1/2) of the Committee members present at such meeting where more than one-half (1/2) of the incumbent Committee members are present.</p>
<p>제6조(의견의 청취) 위원장은 위원회의 심의사항과 관련하여 필요하다고 인정할 때에는 관계인 또는 전문가를 출석시켜 그 의견을 들을 수 있다.</p>	<p>Article 6 (Hearings) The Chairperson shall request relevant parties or experts to attend a Committee meeting and hear opinions when it is deemed necessary for the agenda items under review.</p>
<p>제7조(분과위원회) ①위원회는 위원회의 원활한 운영을 위하여 분야별로 분과위원회를 둘 수 있다.</p>	<p>Article 7 (Subcommittee) ① The Committee may establish a subcommittee for each area to facilitate the smooth operation of the Committee.</p>
<p>②분과위원회는 20명 이내의 위원으로 구성하고, 분과위원장은 분과위원중에서 호선한다.<개정 2010.6.30></p>	<p>② A subcommittee shall consist of less than 20 members and the subcommittee chairperson shall be elected by the subcommittee members from within.<Amended on June 30, 2010></p>

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<p>③분과위원은 해당 분야의 전문적인 지식 및 경험이 풍부한 위원중에서 위원장이 지명한다.</p>	<p>③ The Chairperson shall appoint subcommittee members from among the Committee members who possess in-depth professional knowledge and experience in the relevant area.</p>
<p>④분과위원회 회의는 재적분과위원 과반수의 출석으로 개의하고, 출석분과위원 3분의 2 이상의 찬성으로 의결한다.</p>	<p>④ A subcommittee meeting shall proceed when more than one-half (1/2) of the incumbent subcommittee members are present and shall make a decision by the affirmative vote of more than two-thirds of the subcommittee members present thereat.</p>
<p>⑤분과위원회가 심의·의결한 사항은 위원장이 다른 분과위원회에서 재심의 하여야 할 필요가 있다고 인정하는 경우를 제외하고는 위원회가 심의·의결한 것으로 본다.</p>	<p>⑤ The reviews or decisions made by a subcommittee shall be regarded as final except when the Chairperson determines that it is necessary for it to be reviewed again by another subcommittee.</p>
<p>⑥ 분과위원회의 효율적인 심의를 위하여 분과위원회에 소분과위원회를 둘 수 있다.<신설 2010.6.30></p>	<p>⑥ For efficient review by a subcommittee, a subdivision may be established in the subcommittee.<Newly enacted on June 30, 2010></p>
<p>⑦분과위원회와 소분과위원회의 종류 및 운영 등에 관하여 필요한 사항은 위원회의 의결을 거쳐 보건복지부장관이 정한다.<개정 2008.2.29,2010.3.15,2010.6.30></p>	<p>⑦ The Minister of Health and Welfare shall determine the matters regarding the types and operation of subcommittees and subdivisions thereof approved by the Committee. <Amended on February 29, 2008 and March 15, 2010 and June 30, 2010 respectively></p>
<p>제8조(연구위원) ①위원회는 위원회의 심의사항을 사전에 연구·검토하기 위하여 10인 이내의 연구위원을 둘 수 있다.</p>	<p>Article 8 (Research Members) ① The Committee may have up to ten (10) research members in order to conduct preparatory research and/or preview of the Committee review agenda.</p>
<p>②연구위원은 위원장의 명을 받아 위원회의 심의사항을 미리 조사·연구한다.</p>	<p>② Research members shall conduct preparatory investigation or research into the matters under review by the Committee, the order of the Chairperson.</p>
<p>③연구위원은 위원회의 회의에 출석하여 발언할 수 있다.</p>	<p>③ Research members may attend the Committee meetings and make comments thereat.</p>
<p>④위원회는 연구위원을 보조하게 하기 위하여 10인 이내의 연구원을 둘 수 있다.</p>	<p>④ The Committee may have up to ten (10) researchers in support of research members.</p>
<p>⑤연구위원과 연구원은 의료기기에 관한 전문적인 지식과 경험이 풍부한 자중에서 보건복지부장관이 임명한다. <개정 2008.2.29,2010.3.15></p>	<p>⑤ The Minister of Health and Welfare shall appoint research members and researchers from among persons who possess in-depth professional knowledge and experience in medical devices. < Amended on February 29, 2008 and March 15, 2010, respectively></p>

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<p>제9조(간사와 서기) ①위원회에 간사 1인과 서기 약간인을 둔다.</p> <p>②간사와 서기는 보건복지부 또는 식품의약품안전청 소속공무원중에서 보건복지부장관이 임명한다. <개정 2008.2.29,2010.3.15></p>	<p>Article 9 (Secretary and Clerk) ① The Committee shall have a secretary and some clerks.</p> <p>② The Minister of Health and Welfare shall appoint a secretary and clerks from government officials who belong to the Ministry of Health and Welfare or the Korea Food and Drug Administration. < Amended on February 29, 2008 and March 15, 2010, respectively></p>
<p>제10조(수당과 여비 등) 보건복지부장관은 예산의 범위안에서 위원에게는 수당과 여비를, 제6조의 규정에 따라 위원회에 출석한 전문가에게는 여비를, 연구위원 및 연구원에게는 조사·연구 등을 위한 연구비와 여비를 각각 지급할 수 있다. <개정 2008.2.29,2010.3.15></p>	<p>Article 10 (Compensation and Expenses) The Minister of Health and Welfare may pay compensation and expenses for the Committee members, expenses for experts attending the Committee meetings pursuant to Article 6, and research fund and expenses relating to investigation and research for research members and researchers. < Amended on February 29, 2008 and March 15, 2010, respectively></p>
<p>제11조(과징금의 산정기준) ①법 제33조제2항의 규정에 의한 과징금의 금액은 위반행위의 종별·정도 등을 감안하여 보건복지부령으로 정하는 업무정지처분기준에 따라 별표의 기준을 적용하여 산정한다. <개정 2008.2.29,2010.3.15></p>	<p>Article 11 (Guidelines for Administrative Sanction Fine Calculation) ① The amount of the administrative sanction fine under Paragraph ② of Article 33 of the Act shall be calculated by applying the criteria in the attached table the Ministerial Decree of the Ministry of Health and Welfare, taking the type and degree of a violation into. < Amended on February 29, 2008 and March 15, 2010, respectively></p>
<p>②식품의약품안전청장 또는 시장·군수·구청장(자치구의 구청장을 말한다. 이하 같다)은 의료기기취급자의 사업규모, 위반행위의 정도 및 횟수 등을 참작하여 제1항의 규정에 의한 과징금의 금액의 2분의 1 범위안에서 이를 가중 또는 경감할 수 있다. 다만, 가중하는 경우에도 과징금의 총액은 5천만원 을 초과할 수 없다.</p>	<p>② The KFDA Commissioner, the city mayor, <i>Goon-governor or</i> Gu-governor (meaning the or <i>Gu-governor</i> of an autonomous district unit; same hereinafter) may increase or reduce the amount of administrative sanction fine by up to one half of the amount under Paragraph 1, considering the size of the business of the medical device handler, the degree and frequency of the violation, etc; inthecaseofsuchincrease,thetotalamountoftheadministrative sanction fine shall not exceed 50 million Won.</p>
<p>제12조(과징금의 부과 및 납부절차) ①식품의약품안전청장 또는 시장·군수·구청장이 법 제33조의 규정에 따라 과징금을 부과하고자 하는 때에는 그 위반행위의 종별, 해당 과징금의 금액, 이의방법 및 이의기간 등을 명시하여 이를 납부할 것을 서면으로 통지하여야 한다.</p>	<p>Article 12 (Imposition and Payment of Administrative Sanction Fine) ① In the case that the KFDA Commissioner or the city mayor, <i>Goon-governor or Gu-governor</i> is to impose an administrative sanction fine pursuant to Article 33 of the Act, they shall give written notice requesting payment, which shall specify the type of the violation, the amount of the administrative sanction fine,</p>

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<p>② 제1항의 규정에 따라 통지를 받은 자는 통지를 받은 날부터 20일 이내에 과징금을 식품의약품안전청장 또는 시장·군수·구청장이 정하는 수납기관에 납부하여야 한다. 다만, 천재·지변 그 밖에 부득이한 사유로 인하여 그 기간내에 과징금을 납부할 수 없는 때에는 그 사유가 없어진 날부터 7일 이내에 납부하여야 한다.</p>	<p>the manner and period of filing an objection, etc.</p> <p>② A person who has been given notice under Paragraph 1 shall pay the administrative sanction fine to the collection agency designated by the KFDA Commissioner or the city mayor, <i>Goon</i>-governor or <i>Gu</i>-governor within 20 days from the date he/she receives the notice; provided, however, that if he/she is unable to pay the administrative sanction fine within the said period due to a natural disaster or calamity, or due to any other unavoidable cause, he/she shall pay the administrative sanction fine within 7 days after cessation of such unavoidable cause.</p>
<p>③ 제2항의 규정에 따라 과징금의 납부를 받은 수납기관은 그 납부자에게 영수증을 교부하고, 지체없이 수납사실을 식품의약품안전청장 또는 시장·군수·구청장에게 통보하여야 한다.</p>	<p>③ The collection agency, which receives the administrative sanction fine pursuant to Paragraph 2, shall issue a receipt to the payer, and shall, without delay, notify the KFDA Commissioner or the city mayor, <i>Goon</i>-governor or <i>Gu</i>-governor of the fact of payment.</p>
<p>④ 과징금은 이를 분할하여 납부할 수 없다.</p>	<p>④ The administrative sanction fine shall not be paid in installments.</p>
<p>제12조의2(과징금 미납자에 대한 처분) ① 법 제33조제4항 본문에 따라 식품의약품안전청장, 시장·군수 또는 구청장은 과징금을 내야 할 자가 납부기한까지 내지 아니하면 납부기한이 지난 후 15일 이내에 독촉장을 발부하여야 한다. 이 경우 납부기한은 독촉장을 발부하는 날부터 10일 이내로 하여야 한다.</p>	<p>Article 12-2 (Disposition against Non-payers of Administrative Sanction Fine) ① In case that a person responsible for paying an administrative sanction fine does not pay the administrative sanction fine by the payment deadline, the KFDA Commissioner or the city mayor, <i>Goon</i>-governor or <i>Gu</i>-governor shall, pursuant to the main body of Paragraph 4 of Article 33 of the Act, issue a reminder letter within 15 days after the expiration of the payment deadline. In this case, the new payment deadline shall be within 10 days from the date the reminder letter is issued.</p>
<p>② 제1항에 따라 과징금을 내지 아니한 자가 독촉장을 받고도 납부기한까지 과징금을 내지 아니하면 다음 각 호에 따른 조치를 하여야 한다.</p> <p>1. 과징금 부과처분 대상의 금액이 법 제33조제1항에 따른 과징금 상한액의 2분의 1 이상이면 과징금부과처분을 취소하고 업무정지처분을 할 것</p>	<p>② If the person who has not paid the administrative sanction fine pursuant to Paragraph 1 fails to pay it by the new payment deadline even after he/she receives the reminder letter, one of the following actions shall be taken:</p> <p>1. If the amount of the administrative sanction fine imposed is not less than half of the upper limit of administrative sanction fine under Paragraph 1 of Article 33 of the Act, the imposition of the administrative sanction fine shall be cancelled and suspension of the business operation shall be ordered; or</p>

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
<p>2. 과징금 부과처분 대상의 금액이 법 제33조제1항에 따른 과징금 상한액의 2분의 1 미만이면 국세 또는 지방세의 체납처분의 예에 따라 징수할 것</p>	<p>2. If the amount of the administrative sanction fine imposed is less than half of the upper limit of fine under Paragraph 1 of Article 33 of the Act, it shall be collected in accordance with the procedures for collection of unpaid national or local taxes.</p>
<p>③제2항제1호에 따라 과징금 부과처분을 취소하고 업무정지처분을 하려면 처분대상자에게 서면으로 그 내용을 통지하되, 서면에는 처분이 변경된 사유와 업무정지처분의 기간 등 업무정지처분에 필요한 사항을 기재하여야 한다.[본조신설 2007.7.3]</p>	<p>③ In the case that imposition of the administrative sanction fine is to be cancelled and suspension of the business operation is to be ordered pursuant to Item 1 of Paragraph 2, it shall be notified in writing to the pertinent person subject to administrative sanction fine, and such written notification shall state the specifics necessary for suspension of business operation, such as the reasons for the change from the imposition of the administrative sanction fine to the suspension of the business operation and the period of such suspension of business operation. [Newly added on July 3, 2007]</p>
<p>제13조(권한의 위임) ①법 제37조제1항의 규정에 따라 식품의약품안전청장은 다음 각 호의 권한을 지방식품의약품안전청장에게 위임한다. 다만, 제4호부터 제6호까지 및 제8호의 경우에는 의료기기수리업자에 대한 권한은 제외한다. <개정 2007.7.3,2010.6.30></p> <p>1. 법 제6조제2항의 규정에 의한 품목별 제조신고 및 법 제7조제1항의 규정에 의한 조건부 제조신고의 수리. 다만, 법 제6조제3항의 규정에 따라 제조업허가의 신청과 동시에 품목별 제조신고를 하는 경우를 제외한다.</p> <p>2. 법 제11조제1항(법 제14조제5항의 규정에 따라 준용되는 경우를 포함한다)의 규정에 의한 변경신고의 수리</p> <p>3. 법 제14조제2항의 규정에 의한 품목별 수입신고 및 동조제5항의 규정에 따라 준용되는 법 제7조제1항의 규정에 의한 조건부 수입신고의 수리. 다만, 법 제14조제3항의 규정에 따라 수입업허가의 신청과 동시에 품목별 수입신고를 하는 경우를 제외한다.</p>	<p>Article 13 (Delegation of Authority) ① The Commissioner of KFDA shall delegate the following authorities to the head of the Regional KFDA as referred to in Paragraph 1 of Article 37 of the Act; provided that in case of Items 4 through 6 and Item 8, authority of the Medical Device Refurbisher is excluded. <Amended on July 3, 2007 and June 30, 2010></p> <p>1. Acceptance of a manufacture notification for each product under Paragraph 2 of Article 6 of the Act, and a conditional manufacture notification under Paragraph 1 of Article 7 of the Act, except where a manufacture notification for each product is filed at the same time as a in accordance with Paragraph 3 of Article 6 of the Act.</p> <p>2. Acceptance of an amended notification under Paragraph 1 of Article 11 (including applicable cases under Paragraph 5 of Article 14 of the Act)</p> <p>3. Acceptance of an import notification for each product under Paragraph 2 of Article 14 of the Act, and a conditional import notification under Paragraph 1 of Article 7 of the Act which is applicable pursuant to Paragraph 5 of Article 14, except where an import notification for each product is filed at the same time as an import business for, in accordance with Paragraph 3 of Article 14 of the Act.</p>

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
<p>3의2. 삭제<2010.6.30></p> <p>4. 법 제28조의 규정에 의한 보고명령·출입·검사·질문 및 수거</p> <p>5. 법 제29조의 규정에 의한 검사명령</p> <p>6. 법 제30조의 규정에 의한 회수·폐기 등의 명령 및 봉합·봉인 등의 처분</p> <p>7. 법 제32조의 규정에 의한 품목의 제조금지(법 제6조제2항의 규정에 따라 제조신고한 품목에 한한다), 품목의 수입금지(법 제14조의 규정에 따라 수입신고한 품목에 한한다), 업무의 일부 정지명령 및 수리업자에 대한 업무의 전부정지명령과 이에 갈음한 법 제33조의 규정에 의한 과징금의 부과·징수와 수리업자에 대한 영업소의 폐쇄명령</p> <p>8. 법 제41조의 규정에 의한 신고수리서의 갱신</p> <p>9. 법 제47조의 규정에 의한 과태료의 부과·징수(법 제41조를 위반하여 법 제6조제2항에 따른 제조신고, 법 제14조제2항에 따른 수입신고 및 법 제15조제1항에 따른 수리업신고의 신고수리서를 갱신하지 아니한 경우에 한한다)</p>	<p>3-2. Deleted <June 30, 2010></p> <p>4. Giving an order for reports, or conducting visits, inspections, questioning or collection under Article 28 of the Act</p> <p>5. Giving an order for testing in accordance with Article 29 of the Act</p> <p>6. Giving an order for recalls or destruction, and boxing or sealing under Article 30 of the Act</p> <p>7. Giving an order to prohibit the manufacture of the product under Article 32 of the Act (limited to the products for which manufacture notifications under Paragraph 2 of Article 6 of the Act were filed), an order to prohibit the import of the product (limited to the products for which product import notifications under Article 14 of the Act were filed), an order for the partial suspension of business operation, or an order to a refurbisher for the full suspension of its business operation, and, in lieu thereof, imposition and collection of administrative sanction fine, and closure of business operation against of the refurbisher under Article 33 of the Act.</p> <p>8. Renewal of a notification under Article 41 of the Act</p> <p>9. Imposition and collection of an administrative default fine under Article 47 of the Act (limited to the cases where, in violation of Article 41 of the Act, renewal has not been completed in respect of a manufacture notification under Paragraph 2 of Article 6 of the Act, a product import notification under Paragraph 2 of Article 14, or a notification of refurbishing business under Paragraph 1 of Article 15).</p>
<p>② 식품의약품안전청장은 법 제37조제1항에 따라 다음 각 호의 권한을 특별시장·광역시장·도지사·특별자치도지사에게 위임한다. 다만, 제4호부터 제9호까지의 경우에는 의료기기수리업자에 대한 권한만 해당한다.<신설 2010.6.30></p> <p>1. 법 제15조제1항에 따른 수리업 신고의 수리</p>	<p>② The Commissioner of KFDA shall delegate the following authorities to the mayor of the special metropolitan government, the mayor of the metropolitan city, the provincial governor, and the governor of the special self-governing province Paragraph 1 of Article 37 of the Act; provided that in case of Items 4 through 9, the authority to be delegated shall be limited to the authority over the Medical Device Refurbisher. <Newly enacted on June 30, 2010></p> <p>1. Acceptance of notification of refurbishing business as provided in Paragraph 1</p>

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
<p>2. 법 제15조제4항에 따라 준용되는 법 제11조제1항에 따른 변경신고의 수리</p> <p>3. 법 제15조제4항에 따라 준용되는 법 제13조에 따른 폐업·휴업·재개 또는 변경 신고의 수리</p> <p>4. 법 제28조에 따른 보고명령·출입·검사·질문 및 수거</p> <p>5. 법 제29조에 따른 검사명령</p> <p>6. 법 제30조에 따른 회수·폐기 등의 명령 및 봉합·봉인 등의 처분</p> <p>7. 법 제32조제1항에 따른 영업소의 폐쇄명령 또는 그 업무의 전부 또는 일부의 정지명령과 그 업무정지처분을 갈음한 법 제33조에 따른 과징금의 부과·징수</p> <p>8. 법 제41조에 따른 신고수리서 갱신</p> <p>9. 법 제47조에 따른 과태료의 부과·징수</p>	<p>of Article 15 of the Act</p> <p>2. Acceptance of amended notification as provided in Paragraph 1 of Article 11 of the Act, which is correspondingly applied under Paragraph 4 of Article 15 of the Act</p> <p>3. Acceptance of notification of closure, suspension and resumption of business, or amended notification, as set forth in Article 13 of the Act, which is applied <i>mutatis mutandis</i> under Paragraph 4 of Article 15 of the Act</p> <p>4. Order for report, entry, inspection, questions, and collection as provided in Article 28 of the Act</p> <p>5. Order for testing as provided in Article 29 of the Act</p> <p>6. Order for collection, destruction, etc., and boxing, sealing, etc. as provided in Article 30 of the Act</p> <p>7. Order for shutdown of business place or suspension of part or all of the business as set forth in Paragraph 1 of Article 32 of the Act as provided in Article 33 of the Act, and imposition and collection of an administrative sanction fine in lieu of suspension of business operation as provided in Article 33 of the Act</p> <p>8. Renewal of an accepted notification as provided in Article 41 of the Act</p> <p>9. Imposition and collection of an administrative default fine as provided in Article 47 of the Act</p>
<p style="text-align: center;">부칙 <제18401호, 2004.5.25></p>	<p style="text-align: center;">ADDENDUM <No.18401, May 25, 2004></p>
<p>제1조 (시행일) 이 영은 2004년 5월 30일부터 시행한다.</p>	<p>Article 1 (Effective Date) This Decree shall take effect as of May 30, 2004.</p>
<p>제2조 (다른 법령의 개정) ①동물용의약품등의제조업·수입자와판매업의시설기준령중 다음과 같이 개정한다.</p>	<p>Article 2 (Amendment to Other Relevant Regulations) ① An amendment shall be made in the Standard Ordinance of Facilities for Manufacturers, Importers, and Sellers of Veterinary Drugs as follows:</p>
<p>제2조제1호 및 제6조 제목 및 본문중 “동물용의료용구”를 각각 “동물용의료기기”로 한다.</p>	<p>The “Veterinary Medical Instruments” shall be amended to “Veterinary Medical Device(s)” in the title and the main body of Item 1 of Article 2 and Article 6 respectively.</p>

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
<p>②보건복지부와그소속기관직제중 다음과 같이 개정한다.</p>	<p>② An amendment shall be made to the organization of the Ministry for Health and Welfare, and the agencies and organizations under its supervision, as follows:</p>
<p>제12조제2항제18호 및 제19호중 “의료용구”를 각각 “의료기기”로 한다.</p>	<p>The “Medical Instrument(s)” shall be amended to “Medical Device(s)” in Item 18 and Item 19 of Paragraph 2 of Article 12.</p>
<p>③보건의료기술진흥법시행령중 다음과 같이 개정한다.</p>	<p>③ An amendment shall be made in the Enforcement Decree of the Health and Medical Service Technology Promotion Act as follows:</p>
<p>제2조제3호 가목중 “의료용구”를 “의료기기”로 한다.</p>	<p>“Medical Instrument(s)” shall be amended to “Medical Device(s)” in Sub-item ㉠ of Item 3 of Article 2.</p>
<p>④소득세법시행령중 다음과 같이 개정한다.</p>	<p>④ An amendment shall be made in the Enforcement Decree of the Income Tax Act as follows:</p>
<p>제110조제1항제3호중 “의료용구”를 각각 “의료기기”로 한다.</p>	<p>“Medical Instrument(s)” shall be amended to “Medical Device(s)” in Item 3 of Paragraph 1 of Article 110.</p>
<p>⑤식품의약품안전청과그소속기관직제중 다음과 같이 개정한다.</p>	<p>⑤ An amendment shall be made to the organization of the Korea Food & Drug Administration and its affiliates as follows:</p>
<p>제9조제2항제41호 내지 제49호 및 제10조제8항제1호·제4호·제11호중 “의료용구”를 각각 “의료기기”로 한다.</p>	<p>“Medical Instrument(s)” shall be amended to “Medical Device(s)” in Items 41 through 49 of Paragraph 2 of Article 9, and Items 1, 4 and 11 of Paragraph 8 of Article 10.</p>
<p>⑥약국및의약품등의제조업·수입자와판매업의시설기준령중 다음과 같이 개정한다.</p>	<p>⑥ An amendment shall be made in the Standard Ordinance of Facilities for Pharmacies and Manufacturers, Importers and Sellers of Drugs, etc., as follows:</p>
<p>제3조제1항 각호외의 부분중 “의약품·의약외품 또는 의료용구(이하 “의약품등”이라 한다) 제조소”를 “의약품 또는 의약외품(이하 “의약품등”이라 한다) 제조소”로 한다.</p>	<p>“Manufacturing site for Drugs, Quasi-drugs, or Medical Instruments (hereafter referred to as “Drugs, et al.”)” shall be amended to “Manufacturing site for Drugs or Quasi-drugs (hereafter referred to as “Drugs, et al.”)” in the provisions of Paragraph 1 of Article 3 other than each item thereof.</p>
<p>제9조제2항중 “국민건강보험법 제43조제8항”을 “국민건강보험법 제43조제6항”으로 한다.</p>	<p>“Paragraph 8 of Article 43 of the National Health Insurance Act” shall be amended to “Paragraph 6 of Article 43 of the National Health Insurance Act” in Paragraph 2 of Article 9.</p>
<p>⑦약사법시행령중 다음과 같이 개정한다.</p>	<p>⑦ An amendment shall be made in the Enforcement Decree of the</p>

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
	<p>Pharmaceutical Affairs Law as follows:</p>
<p>제11조제2호중 “의약품·의약외품 및 의료용구(이하 “의약품등”이라 한다)”를 “의약품 및 의약외품(이하 “의약품등”이라 한다)”으로 한다.</p>	<p>“Drugs, Quasi-drugs and Medical Instruments (hereafter referred to as “Drugs, et al.”)” shall be amended to “Drugs and Quasi-drugs (hereafter referred to as “Drugs, et al.”)” in Item 2 of Article 11.</p>
<p>⑧여신전문금융업법시행령중 다음과 같이 개정한다.</p>	<p>⑧ An amendment shall be made in the Enforcement Decree of the Specialized Credit Financial Business Act as follows:</p>
<p>제11조의 제목 및 동조중 “의료용구”를 각각 “의료기기”로 한다.</p>	<p>“Medical Instrument(s)” shall be amended to “Medical Device(s)” in the title and main body of Article 11 respectively.</p>
<p>⑨외국민간원조단체에관한법률시행령중 다음과 같이 개정한다.</p>	<p>⑨ An amendment shall be made in the Enforcement Decree of the Foreign Nongovernmental Aid Organizations Act as follows:</p>
<p>제4조제1호중 “의약품·의약부외품·의료용구·위생용품 및 구급차량”을 “의약품·의약외품·의료기기 및 구급차량”으로 한다.</p>	<p>“Drugs, Quasi-drugs, Medical Instruments, Hygiene articles, and Ambulances” shall be amended to “Drugs, Quasi-drugs, Medical Devices and Ambulances” in Item 1 of Article 4.</p>
<p>⑩행정권한의위임및위탁에관한규정중 다음과 같이 개정한다.</p>	<p>⑩ An amendment shall be made in the Regulation on Delegation and Entrustment of Administrative Authorities, as follows:</p>
<p>제35조제1항제2호 다목중 “의약품(식품의약품안전청장이 정하는 원료의약품을 제외한다)·의약외품 또는 의료용구”를 “의약품(식품의약품안전청장이 정하는 원료의약품을 제외한다) 또는 의약외품”으로 한다.</p>	<p>“Drugs (except for the Pharmaceutical Raw Materials designated by the KFDA Commissioner), Quasi-drugs or Medical Instruments” shall be amended to “Drugs (except for the Pharmaceutical Substances designated by the KFDA Commissioner) or Quasi-drugs” in sub-item ㉠ of Item 2 of Paragraph 1 of Article 35.</p>
<p style="text-align: center;">부칙 <제19513호, 2006.6.12>(고위공무원단 인사규정)</p>	<p style="text-align: center;">ADDENDUM (Staff Regulations of Senior Civil Service) <No.19513, June 12, 2006></p>
<p>제1조 (시행일) 이 영은 2006년 7월 1일부터 시행한다.</p>	<p>Article 1 (Effective Date) This Decree shall take effect as of July 1, 2006.</p>
<p>제2조 및 제3조 생략</p>	<p>Articles 2 and 3 Omitted</p>
<p>제4조 (다른 법령의 개정) ①내지 <161>생략</p>	<p>Article 4 (Amendment to Other Relevant Regulations) Paragraph 1 through <161> Omitted.</p>
<p><162>의료기기법시행령 일부를 다음과 같이 개정한다.</p>	<p>An amendment shall be made in the <162> Enforcement Decree of the Medical Device Act in part as follows:</p>

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
<p>제2조제3항제1호중 “4급이상의 공무원”을 “4급 이상의 공무원 또는 고위공무원단에 속하는 일반직공무원”으로 한다.</p>	<p>“Public officials of 4th grade or higher” of Item 1 of Paragraph 3 of Article 2 shall be amended to “Public officials of 4th grade or higher, or those of general position belonging to Senior Civil Service”.</p>
<p><163>내지 <241>생략</p>	<p><163 > through <241> Omitted.</p>
<p style="text-align: center;">부칙 <제20157호, 2007.7.3></p>	<p style="text-align: center;">ADDENDUM <No.20157, July 3, 2007></p>
<p>이 영은 2007년 7월 4일부터 시행한다. 다만, 제13조의 개정규정은 공포 후 30일이 경과한 날부터 시행한다.</p>	<p>This Decree shall take effect from July 4, 2007 provided that the amended provision of Article 13 shall take effect 30 days from the date of promulgation.</p>
<p style="text-align: center;">부칙 <제20679호, 2008.2.29>(보건복지가족부와 그 소속기관 직제)</p>	<p style="text-align: center;">ADDENDUM (Organization of the Ministry for Health, Welfare and Family Affairs and its Affiliates) <No. 20679, February 29, 2008 ></p>
<p>제1조(시행일) 이 영은 공포한 날부터 시행한다.</p>	<p>Article 1 (Effective Date) This Decree shall take effect as of the date of promulgation.</p>
<p>제2조부터 제8조까지 생략</p>	<p>Articles 2 through 8 Omitted.</p>
<p>제9조(다른 법령의 개정) ① 부터 <47> 까지 생략</p>	<p>Article 9 (Amendment to Other Relevant Regulations) Paragraph 1 through <47> Omitted.</p>
<p><48> 의료기기법 시행령 일부를 다음과 같이 개정한다.</p>	<p>An amendment shall be made in the <48> Enforcement Decree of the Medical Device Act in part as follows:</p>
<p>제2조제2항 중 “보건복지부차관”을 “보건복지가족부차관”으로 한다.</p>	<p>The “Vice-Minister of Health and Welfare” of Paragraph 2 of Article 2 shall be amended to the “Vice-Minister for Health, Welfare and Family Affairs”.</p>
<p>제2조제3항 각 호 외의 부분, 제5조제2항, 제7조제6항, 제8조제5항 및 제10조 중 “보건복지부장관”을 각각 “보건복지가족부장관”으로 한다.</p>	<p>The “Minister of Health and Welfare” shall be each amended to the “Minister of Health, Welfare and Family Affairs” in Paragraph 3 of Article 2 other than each item thereof, Paragraph 2 of Article 5, Paragraph 6 of Article 7, Paragraph 5 of Article 8, and Article 10 respectively.</p>
<p>제9조제2항 중 “보건복지부”를 “보건복지가족부”로, “보건복지부장관”을 “보건복지가족부장관”으로 한다.</p>	<p>The “Ministry of Health and Welfare” shall be amended to the “Minister for Health, Welfare and Family Affairs” and the “Minister of Health and Welfare” to the “Minister of Health, Welfare and Family Affairs” in Paragraph 2 of Article 9.</p>
<p>제11조제1항 중 “보건복지부령”을 “보건복지가족부령”으로 한다.</p>	<p>The “Ministerial Decree of the Ministry of Health and Welfare” of Paragraph 1 of Article 11 shall be amended to the “Ministerial Decree of the Ministry for</p>

<p style="text-align: center;">의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30]</p>	<p style="text-align: center;">Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010]</p>
	Health, Welfare and Family Affairs”.
<49> 부터 <80> 까지 생략	<49> through <80> Omitted.
부칙 <제22075호, 2010.3.15>	ADDENDUM <No. 22075, March 15, 2010>
제1조(시행일) 이 영은 2010년 3월 19일부터 시행한다. <단서 생략>	Article 1 (Effective Date) This Decree shall take effect as of March 19, 2010.
제2조(다른 법령의 개정) ① 부터 <119> 까지 생략	Article 2 (Amendment to Other Relevant Regulations) Paragraphs 1 through <119> shall be omitted.
<120> 의료기기법 시행령 일부를 다음과 같이 개정한다.	<120> The Medical Device Ordinance shall be amended partially as follows:
제2조제2항 중 “보건복지가족부차관”을 “보건복지부차관”으로 한다.	“Vice-Minister of Health, Welfare and Family Affairs” shall be amended to the “Vice-Minister for Health and Welfare” in Paragraph 2 of Article 2.
제2조제3항 각 호 외의 부분, 제5조제2항, 제7조제6항, 제8조제5항, 제9조제2항 및 제10조 중 “보건복지가족부장관”을 각각 “보건복지부장관”으로 한다.	“Minister of Health and Welfare” shall be amended to “Minister for Health, Welfare and Family Affairs” in Paragraph 3 of Article 2 other than each item thereof, Paragraph 2 of Article 5, Paragraph 6 of Article 7, Paragraph 5 of Article 8 Paragraph 2 of Article 9 and Article 10.
제9조제2항 중 “보건복지가족부”를 “보건복지부”로 한다.	“Ministry of Health, Welfare and Family Affairs” of Paragraph 2 of Article 9 shall be amended to “Minister for Health and Welfare”.
제11조제1항 중 “보건복지가족부령”을 “보건복지부령”으로 한다.	“Ministerial Decree of the Ministry of Health, Welfare and Family Affairs” of Paragraph 1 of Article 11 shall be amended to “Ministerial Decree of the Ministry of Health and Welfare”.
<121> 부터 <187> 까지 생략	<121> through <187> Omitted.
부칙 <제22247호,2010.6.30>	ADDENDUM <No.22247, June 30, 2010>
제1조(시행일) 이 영은 2011년 1월 1일부터 시행한다. 다만, 제7조의 개정규정은 공포한 날부터 시행한다.	Article 1 (Effective Date) This Decree shall take effect as of January 1, 2011. However, the provisions of Article 7 as amended shall take effect from the date of promulgation.
제2조(처분 등에 관한 경과조치) 이 영 시행 당시 종전의 규정에 따른 행정기관의 의료기기수리업 신고의 수리, 처분 및 그 밖의 행위는 그에 해당하는 이 영에 따른 행정기관의 의료기기수리업 신고의 수리, 처분 및 그 밖의 행위로 보고, 종전의 규정에 따른 행정기관에 대한 신고 및 그 밖의 행위는 그에 해당하는 이 영에 따른 행정기관에 대한 신고 및 그 밖의 행위로 본다.	Article 2 (Interim Measures concerning Disposition, Etc.) Acceptance, disposition or other acts by an administrative body in respect of a refurbishing business notification for medical devices under the previous provisions in effect as of the effective date of this Decree shall be deemed to be the acceptance, disposition or other acts by an administrative body in respect of a refurbishing business

<p style="text-align: center;"> 의료기기법 시행령 [시행 2011.1.1] [대통령령 제22247호, 2010.6.30] </p>	<p style="text-align: center;"> Enforcement Decree of the Medical Device Act [Effective as of January 1, 2010] [Presidential Decree No. 22075, March 15, 2010] </p>
	<p>notification for medical devices under this Decree, and notifications and other acts to an administrative body under such previous provisions shall be deemed to be notifications and other acts to an administrative body under this Decree.</p>