General Information on Draft Partial Amendment to the Regulation for Registration of Medical Devices

This Regulation was established in accordance with Paragraph 3, Article 40 of the Pharmaceutical Affairs Act to meet the needs for registration and market approval of medical devices and management of permit licenses, and was promulgated and came into force as per the Decree of Wei-Shu-Yao-Zi No. 0930328238 on December 30, 2004. This Regulation has undergone five amendments since then. In order to improve the registration and market approval process and ensure the safety and efficacy of medical devices on the market, a draft partial amendment to the Regulation for Registration of Medical Devices has been formulated. The main points of the amendment are as follows:

1. With the provisions of Paragraph 3 of Article 3 and Article 13 of the Regulations for Registration of Medicinal Products as reference, it is stipulated that a Chinese or English translation shall be provided if the documents submitted are not made in Traditional Chinese or English (amendment to Article 3).
2. Considering that the current relationship between the commissioning company and the commissioned manufacturing factory is not proved by a manufacture certificate but by a commissioning contract signed by the parties and other relevant documents in accordance with the Regulations for Medicament Contract Manufacture and Analysis, the relevant provisions that require a clear description of the relationship between the commissioning company and the commissioned manufacturing factory in a manufacture and free sale certificate of the country of origin, as set forth in the latter part of Paragraph 3, are deleted (amendment to Article 7).
3. To meet the needs for e-government, online application services have

become available for Class I medical devices. The applicant may sign or affix their seal to confirm their identity if an application is submitted in writing. However, if a registration application is submitted online, the identity of the applicant must be confirmed by means of electronic signature since the applicant is unable to sign or affix their seal. As a result, the latter part of the paragraph explicitly stipulates that those submitting an application online shall do so with the IC card issued by the Certificate Authority of the Ministry of Economic Affairs (amendment to Articles 14 and 16).

4. Changes in the specifications or efficacy of a medical device shall be done after evaluated by the original designer or manufacturer of the product, so as to ensure the safety and efficacy of the product. Therefore, the amendment requires that the comparison and explanation of the changed specifications or efficacy and the originally approved specifications or efficacy submitted for the purpose of applying for change of the specifications or efficacy on a permit license shall be issued by the original medical device manufacturer (amendment to Articles 24 and 26).
5. Paragraph 6 is added to prevent the change of the address of a medical device manufacturing factory from resulting in any inconsistency with its medical device previously approved for registration and market approval in terms of the quality, safety, and efficacy. The central competent authority may order the applicant to submit relevant supporting documents to confirm the consistency with its medical device previously approved for registration and market approval (amendment to Article 28).
6. To avoid other factors that affect the safety and efficacy of the product concerned due to extension or change of a permit license, the rights of the central health competent authority to order the applicant to submit relevant documents are reserved, thereby ensuring the efficacy and safety of the product (amendment to Article 35).
7. To collect complete information on the instructions of Class I medical

devices and improve the management after launch to the market, it is explicitly stipulated that Class I medical device permit license holders shall upload the instructions, labels, and outer box documents to the information system specified by the central health competent authority within one (1) month after obtaining permit licenses or within six (6) months after the amendment to this Regulation comes into force if they obtain Class I medical device permit licenses before the amendment to this Regulation comes into force. Moreover, such uploading is listed as a requirement for applying for extension of Class I medical device permit licenses (amendment to Articles 35 and 36).

8. Since the review process for medical devices exclusively for export is different from that for domestically manufactured medical devices, it is explicitly stipulated that the Chinese and English names of medical devices exclusively for export shall not be the same as those of domestically manufactured medical devices. Thus, any confusion between medical devices exclusively for export and domestically manufactured medical devices can be avoided (amendment to Article 37).

Comparison Table of Provisions of the Draft Partial Amendment to the Regulation for Registration of Medical Devices

Amended Provisions	Existing Provisions	Explanations
Article 3 For all registrations mentioned in the preceding article, the applicant shall pay the application fee and submit completed application forms with all required documents pursuant to this Regulation to the central health competent authority for approval. The application forms referred to in the foregoing Paragraph include application form for the registration and market approval of medical devices, application form for change of registration, application form for extension of permit license validity, affidavit, form for attaching outer box instruction label, and other form and document formats associated with the application procedures. If the documents submitted for an application filed in accordance	Article 3 For all registrations mentioned in the preceding article, the applicant shall pay the application fee and submit completed application forms with all required documents pursuant to this Regulation to the central health competent authority for approval. The application forms referred to in the foregoing Paragraph include application form for the registration and market approval of medical devices, application form for change of registration, application form for extension of permit license validity, affidavit, form for attaching outer box instruction label, form for attaching permit license, and other form and document formats associated with the application procedures.	1. The “form for attaching permit licenses”, as previously set forth in Paragraph 2, is provided for a manufacturer to attach its pharmaceutical firm permit license. However, the provisions governing the required application documents herein have stipulated that a pharmaceutical firm permit license and other documents shall be submitted. Therefore, an applicant shall directly submit a photocopy of its license, and said form is deleted. 2. Paragraph 3 is added to stipulate that a Traditional Chinese or English translation shall be provided if the documents submitted for an application filed in accordance with this Regulation are not in Traditional Chinese or English.

Amended Provisions	Existing Provisions	Explanations
with this Regulation are not in Traditional Chinese or English, a Traditional Chinese or English translation shall be provided.		
Article 7 The manufacture and free sale certificates of the country of origin referred to in this Regulation are verifying documents issued by the highest health authority of the country where the imported medical device is manufactured. The content of such documents shall state the name and the address of the manufacturing factory, the name of the medical device, the specifications and model of the medical device, the circumstances of manufacture, and the certification of approval for domestic sale in that country. If it is confirmed that the medical device is not regulated by the highest health authority in the country of the manufacturer, said manufacturing and sales approval documents may be issued by the local health agency or an organization approved by	Article 7 The manufacture and free sale certificates of the country of origin referred to in this Regulation are verifying documents issued by the highest health authority of the country where the imported medical device is manufactured. The content of such documents shall state the name and the address of the manufacturing factory, the name of the medical device, the specifications and model of the medical device, the circumstances of manufacture, and the certification of approval for domestic sale in that country. If it is confirmed that the medical device is not regulated by the highest health authority in the country of the manufacturer, said manufacturing and sales approval documents may be issued by the local health agency or an organization approved by	Paragraph 3 is amended. The current relationship between the commissioning company and the commissioned manufacturing factory is proved by a commissioning contract. Thus, “the documents shall provide clear description about the relationship between the commissioning company and commissioned manufacturing factory” is deleted.

Amended Provisions	Existing Provisions	Explanations
Taiwan's central health competent authority. With regard to the manufacture and free sale certificates in the foregoing Paragraph, if an imported medical device is commissioned to manufacture, and the device is not on sale in the country of the commissioned manufacturing factory, a free sale certificate issued from the country's highest competent health authority of the commissioning company and a manufacture certificate issued from the country's competent authority of commissioned manufacturing factory may be submitted instead of the foregoing manufacture and free sale certificate. If an imported medical device is commissioned to be manufactured, the manufacture and free sale certificates in Paragraph 1 are allowed to be issued by respective highest health competent authority of the country either of the commissioning company or of the commissioned	Taiwan's central health competent authority. With regard to the manufacture and free sale certificates in the foregoing Paragraph, if an imported medical device is commissioned to manufacture, and the device is not on sale in the country of the commissioned manufacturing factory, a free sale certificate issued from the country's highest competent health authority of the commissioning company and a manufacture certificate issued from the country's competent authority of commissioned manufacturing factory may be submitted instead of the foregoing manufacture and free sale certificate. If an imported medical device is commissioned to be manufactured, the manufacture and free sale certificates in Paragraph 1 are allowed to be issued by respective highest health competent authority of the country either of the commissioning company or of the commissioned	

Amended Provisions	Existing Provisions	Explanations
manufacturing factory. The manufacture and free sale certificates in Paragraph 1 is allowed to be substituted by a certificate of manufacture issued by the government of the country where the imported medical device is manufactured and a certificate of free sale issued by the highest health competent authority of the United States of America, or any member state of the European Union. The verifying documents in the four preceding paragraphs shall remain valid for two years after the date of issuance, and shall be notarized by Taiwan's embassy or consulate, representative office, other official office, or overseas organization in that country authorized by the Ministry of Foreign Affairs (hereafter referred to as the overseas representative organization of Taiwan). A Chinese or English translation shall be attached when the verifying documents are not in English,	manufacturing factory. <u>The documents shall provide clear description about the relationship between the commissioning company and commissioned manufacturing factory.</u> The manufacture and free sale certificates in Paragraph 1 is allowed to be substituted by a certificate of manufacture issued by the government of the country where the imported medical device is manufactured and a certificate of free sale issued by the highest health competent authority of the United States of America, or any member state of the European Union. The verifying documents in the four preceding paragraphs shall remain valid for two years after the date of issuance, and shall be notarized by Taiwan's embassy or consulate, representative office, other official office, or overseas organization in that country authorized by the Ministry of Foreign Affairs (hereafter referred	

Amended Provisions	Existing Provisions	Explanations
and the translation shall also be notarized.	to as the overseas representative organization of Taiwan). A Chinese or English translation shall be attached when the verifying documents are not in English, and the translation shall also be notarized.	
Article 14 For application of registration and market approval of domestically manufactured Class 1 medical devices, the following documents shall be submitted for review: 1. Application form for Class 1 medical device registration and market approval and original copy of affidavit. 2.A photocopy of pharmaceutical firm permit license as a medical device manufacturer. 3.Documents verifying that the manufactory in conformity with the Good Manufacturing Practices for Medical Devices in accordance with the Part 3 of the Pharmaceutical Good Manufacturing Practice Regulations (hereafter referred to as GMP for Medical Devices). Prod-	Article 14 For application of registration and market approval of domestically manufactured Class 1 medical devices, the following documents shall be submitted for review: 1. Application form for Class 1 medical device registration and market approval and original copy of affidavit. 2.A photocopy of pharmaceutical firm permit license as a medical device manufacturer. 3.Documents verifying that the manufactory in conformity with the Good Manufacturing Practices for Medical Devices in accordance with the Part 3 of the Pharmaceutical Good Manufacturing Practice Regulations (hereafter referred to as GMP for Medical Devices). Prod-	Paragraph 5 is added. Online application becomes available to meet the needs for e-government. In addition, it is explicitly stated that the applicant shall sign or affix their seal if an application is submitted in writing. If a registration application is submitted online, the identity of the applicant must be confirmed by means of electronic signature since the applicant is unable to sign or affix their seal. As a result, the latter part of the paragraph explicitly stipulates that those submitting an application online shall do so with the IC card issued by the Certificate Authority of the Ministry of Economic Affairs. Moreover, the pharmaceutical firm permit licenses of those submitting an application online may be inspected on

Amended Provisions	Existing Provisions	Explanations
uct items in accordance with the Article 4 Appendix II of the Regulations for Governing the Management of Medical Device are exempted from this subparagraph. In the event of the pharmaceutical firm applying for registration different from the manufacturer, it shall be deemed as commission manufacturing. The medical device applying for registration is commissioned to manufacture or analysis, it shall be in conformity with the Regulations for Medicament Contract Manufacture and Analysis. The medical device applying for registration in Paragraph 1 shall be in conformity with proclamations of the central health competent authority; and the technical documentation of the device shall be kept in the manufactory for inspection, which including: the Chinese instruction leaflet, instruction for use, packaging, labels of the medical device, and doc-	uct items in accordance with the Article 4 Appendix II of the Regulations for Governing the Management of Medical Device are exempted from this subparagraph. In the event of the pharmaceutical firm applying for registration different from the manufacturer, it shall be deemed as commission manufacturing. The medical device applying for registration is commissioned to manufacture or analysis, it shall be in conformity with the Regulations for Medicament Contract Manufacture and Analysis. The medical device applying for registration in Paragraph 1 shall be in conformity with proclamations of the central health competent authority; and the technical documentation of the device shall be kept in the manufactory for inspection, which including: the Chinese instruction leaflet, instruction for use, packaging, labels of the medical device, and documents	the system. Therefore, the applying pharmaceutical firms are not required to provide said documents.

Amended Provisions	Existing Provisions	Explanations
uments with the product information such as construction, material, specification, efficacy, purpose, drawing and others, and documents of pre-clinical trial, and inspection results of quality control of original manufacturer. The central health competent authority may order its submission if necessary. The registration and market approval application filed in accordance with Paragraph 1 may be submitted in writing or online. In the case of submission in writing, the applying pharmaceutical firm shall sign or affix their seal to the application form. In the case of submission online, the IC card issued by the Certificate Authority of the Ministry of Economic Affairs shall be used, and the documents set forth in Subparagraphs 1 and 2 of Paragraph 1 are not required.	with the product information such as construction, material, specification, efficacy, purpose, drawing and others, and documents of pre-clinical trial, and inspection results of quality control of original manufacturer. The central health competent authority may order its submission if necessary.	
Article 15 For application of registration and market approval for domestically manufactured Class 2 or	Article 15 For application of registration and market approval for domestically manufactured Class 2 or	1. The text in Subparagraph 2 of Paragraph 2 is amended. 2. Paragraph 7 is amended. For medical devices that

Amended Provisions	Existing Provisions	Explanations
Class 3 medical devices, the following documents shall be submitted for review: 1.One copy each of the original and photocopy of the medical device registration and market approval application form. 2.Two copies of each of the following items: the form for attaching outer box instruction label with all Chinese instruction leaflet catalog packaging, and labeling, instructions for use, and color pictures of the physical appearance of product. 3.A photocopy of pharmaceutical firm permit license as a medical device manufacturer. 4.Affidavit (A) 5.Documents verifying that the domestic manufacturing factory is in conformity with the GMP for Medical Devices. 6.One copy of each of the follwing items: preclinical testing and the test specifications and methods, the original	Class 3 medical devices, the following documents shall be submitted for review: 1.One copy each of the original and photocopy of the medical device registration and market approval application form. 2.Two copies of each of the following items: the form for attaching outer box instruction label with all Chinese instruction leaflet catalog packaging, and labeling, instructions for use, and color pictures of the physical appearance of product. 3.A photocopy of pharmaceutical firm permit license as a medical device manufacturer. 4.Affidavit (A) 5.Documents verifying that the domestic manufacturing factory is in conformity with the GMP for Medical Devices. 6.One copy of each of the follwing items: preclinical testing and the test specifications and methods, the original	require submission for testing, two (2) copies of the documents stating the test specifications and methods for preclinical testing and quality control conducted by the original manufacturer, the original test records, and the test result reports shall be submitted.

Amended Provisions	Existing Provisions	Explanations
test records, and the test reports of the quality control conducted by the original manufacturer. 7.One copy of each of the relevant documents concerning product structure, materials, specifications, performance, intended uses, and drawings, etc. For instrument products, an operation manual or a service manual covers all of the above-mentioned items may be a substitution. 8.Theoretical basis and relevant research reports and data. 9.Clinical trial reports. 10.Two copies of radiation safety information for equipments generating ionizing radiation. Documents of the Subparagraphs 5 in the preceding paragraph, in accordance with any of the followings, may be substituted with photocopies of documents verifying compliance with the Good Manufacturing Practices for Pharmaceuticals in accordance with	test records, and the test reports of the quality control conducted by the original manufacturer. 7.One copy of each of the relevant documents concerning product structure, materials, specifications, performance, intended uses, and drawings, etc. For instrument products, an operation manual or a service manual covers all of the above-mentioned items may be a substitution. 8.Theoretical basis and relevant research reports and data. 9.Clinical trial reports. 10.Two copies of radiation safety information for equipments generating ionizing radiation. Documents of the Subparagraphs 5 in the preceding paragraph, in accordance with any of the followings, may be substituted with photocopies of documents verifying compliance with the Good Manufacturing Practices for Pharmaceuticals in accordance with	

Amended Provisions	Existing Provisions	Explanations
the Part 2 of the Pharmaceutical Good Manufacturing Practice Regulations (hereafter referred to as GMP for Pharmaceuticals): 1.The medical device applying for registration and market approval was regulated as pharmaceutical product before. This rule applies within three years from the date of proclamations of listing change. 2.The medical device was regulated as a pharmaceutical product before January 1, 2013. This rule applies within three years from the promulgation date of the September 5, 2014 amendment to this Regulation. The central health competent authority shall determine or announce whether the medical device applying for registration and market approval requires clinical trials in Taiwan in light of the medical device product item, the case, and the materials submitted. In the event of al-	the Part 2 of the Pharmaceutical Good Manufacturing Practice Regulations (hereafter referred to as GMP for Pharmaceuticals): 1.The medical device applying for registration and market approval was regulated as pharmaceutical product before. This rule applies within three years from the date of proclamations of listing change. 2.The medical device was regulated as a pharmaceutical product before January 1, 2013. This rule applies within three years from the promulgation date of the September 5, 2014 amendment to this Regulation. The central health competent authority shall determine or announce whether the medical device applying for registration and market approval requires clinical trials in Taiwan in light of the medical device product item, the case, and the materials submitted. In the event of al-	

Amended Provisions	Existing Provisions	Explanations
ready a product in the market similar to the medical device applying for registration, except where other regulations apply, the documents specified in Subparagraphs 8 and 9 of Paragraph 1 may be waived. However, the applicant shall additionally attach a domestic clinical trial report when clinical trials in Taiwan are required in accordance with the foregoing Paragraph. In the event of applying for registration and market approval of Class 2 medical devices with no predicate product previously approved to market by the central health competent authority, the documents specified in Subparagraphs 9 of Paragraph 1 may be waived if the medical device is in conformity with the related simplified rules or regulations announced by the central health competent authority. However, a domestic clinical trial report shall be submitted when a domestic clinical trial is required according	ready a product in the market similar to the medical device applying for registration, except where other regulations apply, the documents specified in Subparagraphs 8 and 9 of Paragraph 1 may be waived. However, the applicant shall additionally attach a domestic clinical trial report when clinical trials in Taiwan are required in accordance with the foregoing Paragraph. In the event of applying for registration and market approval of Class 2 medical devices with no predicate product previously approved to market by the central health competent authority, the documents specified in Subparagraphs 9 of Paragraph 1 may be waived if the medical device is in conformity with the related simplified rules or regulations announced by the central health competent authority. However, a domestic clinical trial report shall be submitted when a domestic clinical trial is required according	

Amended Provisions	Existing Provisions	Explanations
to Paragraph 3. In the event of applying for registration of medical devices exclusively for export, submissions for testing are not required, and documents required by Subparagraphs 6 to 10 of Paragraph 1 shall be exempted. The registration and market approval of IVDs shall be in conformity with the preceding six paragraphs and announcements by the central health competent authority. For the IVDs listed as Class III according to the Regulations for Governing the Management of Medical Device and required to undergo testing, as announced by the central health competent authority, two (2) copies of the documents specified in Subparagraph 6 of Paragraph 1 shall be submitted, and submission for testing is required, except for products exclusively for export. The medical devices applying for Class III regis-	to Paragraph 3. In the event of applying for registration of medical devices exclusively for export, submissions for testing are not required, and documents required by Subparagraphs 6 to 10 of Paragraph 1 shall be exempted. IVD applying for registration and market approval shall be in conformity with the preceding six paragraphs and proclamations by the central health competent authority; the IVDs listed as Class III according to the Regulations for Governing the Management of Medical Device and announced by the central health competent authority for the requirement of testing shall also submit for testing, except products exclusively for export. The medical devices applying for Class III registration and market approval, except products exclusively for export, shall also submit documents of Essential Princi-	

Amended Provisions	Existing Provisions	Explanations
tration and market approval, except products exclusively for export, shall also submit documents of Essential Principles (EP) and Summary of Technical Documentation (STED) in accordance with Appendix. In the event of the pharmaceutical firm applying for registration and market approval different from the manufacturer, it shall be deemed as commission manufacturing. In the event of the medical device applying for registration and market approval is commissioned to manufacture or testing, the device shall be in conformity with the preceding nine paragraphs and the Regulations for Medicament Contract Manufacture and Analysis. The medical device applying for registration in Paragraph 1 and Paragraph 6 shall be in conformity with related rules or regulations announced by the central health competent authority, and the documents exempted	ples (EP) and Summary of Technical Documentation (STED) in accordance with Appendix. In the event of the pharmaceutical firm applying for registration and market approval different from the manufacturer, it shall be deemed as commission manufacturing. In the event of the medical device applying for registration and market approval is commissioned to manufacture or testing, the device shall be in conformity with the preceding nine paragraphs and the Regulations for Medicament Contract Manufacture and Analysis. The medical device applying for registration in Paragraph 1 and Paragraph 6 shall be in conformity with related rules or regulations announced by the central health competent authority, and the documents exempted from submission shall be kept in the manufacturing factory. The central health competent authority may order its submis-	

Amended Provisions	Existing Provisions	Explanations
from submission shall be kept in the manufacturing factory. The central health competent authority may order its submission when necessary.	sion when necessary.	
Article 16 For application of registration and market approval for imported Class I medical device, the following documents shall be submitted: 1.Application form for Class I medical device registration and market approval and original copy of affidavit. 2.A photocopy of pharmaceutical firm permit license as a medical device dealer. 3.Certificate of in conformity with the GMP for Medical Devices. Product items in accordance with the Article 4 Appendix II of the Regulations for Governing the Management of Medical Device are exempted from this subparagraph. If the medical device applying for registration and market approval is commissioned to manufacture or analysis, it shall	Article 16 For application of registration and market approval for imported Class I medical device, the following documents shall be submitted: 1.Application form for Class I medical device registration and market approval and original copy of affidavit. 2.A photocopy of pharmaceutical firm permit license as a medical device dealer. 3.Certificate of in conformity with the GMP for Medical Devices. Product items in accordance with the Article 4 Appendix II of the Regulations for Governing the Management of Medical Device are exempted from this subparagraph. If the medical device applying for registration and market approval is commissioned to manufacture or analysis, it shall	Paragraph 4 is added. Online application becomes available to meet the needs for e-government. In addition, it is explicitly stated that the applicant shall sign or affix their seal if an application is submitted in writing. If a registration application is submitted online, the identity of the applicant must be confirmed by means of electronic signature since the applicant is unable to sign or affix their seal. As a result, the latter part of the paragraph explicitly stipulates that those submitting an application online shall do so with the IC card issued by the Certificate Authority of the Ministry of Economic Affairs.

Amended Provisions	Existing Provisions	Explanations
be in conformity with the Regulations for Medicament Contract Manufacture and Analysis. The medical device applying for registration in the Paragraph 1 shall be in conformity with related rules or regulations announced by the central health competent authority, and the following technical documentation of the device shall be kept in the manufacturing factory for inspection: instruction leaflets, the original instruction for use with a copy of its Chinese translation, packaging, labels of the medical device, and documents with the information of the product such as structure, materials, specifications, performance, intended use, drawing and others, and documents of pre-clinical testing, and the testing results of quality control of the original manufacturer. The central health competent authority may order its submission when necessary. <u>The registration and</u>	be in conformity with the Regulations for Medicament Contract Manufacture and Analysis. The medical device applying for registration in the Paragraph 1 shall be in conformity with related rules or regulations announced by the central health competent authority, and the following technical documentation of the device shall be kept in the manufacturing factory for inspection: instruction leaflets, the original instruction for use with a copy of its Chinese translation, packaging, labels of the medical device, and documents with the information of the product such as structure, materials, specifications, performance, intended use, drawing and others, and documents of pre-clinical testing, and the testing results of quality control of the original manufacturer. The central health competent authority may order its submission when necessary.	

Amended Provisions	Existing Provisions	Explanations
market approval application filed in accordance with Paragraph 1 may be submitted in writing or online. In the case of submission in writing, the applicant shall sign or affix their seal to the application form. In the case of submission online, the IC card issued by the Certificate Authority of the Ministry of Economic Affairs shall be used, and the documents set forth in Subparagraphs 1 and 2 of Paragraph 1 are not required.		
Article 17 For application of registration and market approval for imported Class II or Class III medical devices, the following document shall be submitted for review: 1.One copy of each of the original and photocopy of the medical device registration and market approval application form. 2.Two copies of each of the following items: the affixed or stapled to the label attachment form of instructions and manual with detailed	Article 17 For application of registration and market approval for imported Class II or Class III medical devices, the following document shall be submitted for review: 1.One copy of each of the original and photocopy of the medical device registration and market approval application form. 2.Two copies of each of the following items: the affixed or stapled to the label attachment form of instructions and manual with detailed	1. The text in Subparagraph 2 of Paragraph 2 is amended. 2. Paragraph 6 is amended. For medical devices that require submission for testing, two (2) copies of the documents stating the test specifications and methods for preclinical testing and quality control conducted by the original manufacturer, the original test records, and the test result reports shall be submitted.

Amended Provisions	Existing Provisions	Explanations
Chinese translations, packaging, labels and color pictures of the physical appearance of product. 3.A photocopy of pharmaceutical firm permit license as a medical device dealer. 4.Affidavit (A) 5.The original copy of the manufacture and free sale certificate of the country of origin. 6.The original copy of the foreign original manufacturer authorization letter. 7.Documents verifying that the domestic manufacturing factory in conformity with the GMP for Medical Devices. 8.One copy of each of the following items: preclinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer. 9.One copy of each of the relevant documents concerning product	Chinese translations, packaging, labels and color pictures of the physical appearance of product. 3.A photocopy of pharmaceutical firm permit license as a medical device dealer. 4.Affidavit (A) 5.The original copy of the manufacture and free sale certificate of the country of origin. 6.The original copy of the foreign original manufacturer authorization letter. 7.Documents verifying that the domestic manufacturing factory in conformity with the GMP for Medical Devices. 8.One copy of each of the following items: preclinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer. 9.One copy of each of the relevant documents concerning product	

Amended Provisions	Existing Provisions	Explanations
structure, materials, specifications, performance, intended uses, and drawings, etc. For instrument product, an operation manual or a service manual covers all of the abovementioned items may be a substitution. 10.Theoretical basis and relevant research reports and data. 11.Clinical trial reports. 12.Two copies of radiation safety information for equipment generating ionizing radiation. Documents of the Subparagraphs 7 in the preceding paragraph, in accordance with any of the followings, may be substituted with photocopies of documents verifying compliance with the GMP for Pharmaceuticals: 1.The medical device applying for registration and market approval was regulated as pharmaceutical product before. This rule applies within three years from the date of proclamations of listing change.	structure, materials, specifications, performance, intended uses, and drawings, etc. For instrument product, an operation manual or a service manual covers all of the abovementioned items may be a substitution. 10.Theoretical basis and relevant research reports and data. 11.Clinical trial reports. 12.Two copies of radiation safety information for equipment generating ionizing radiation. Documents of the Subparagraphs 7 in the preceding paragraph, in accordance with any of the followings, may be substituted with photocopies of documents verifying compliance with the GMP for Pharmaceuticals: 1.The medical device applying for registration and market approval was regulated as pharmaceutical product before. This rule applies within three years from the date of proclamations of listing change.	

Amended Provisions	Existing Provisions	Explanations
2.The medical device was regulated as a pharmaceutical product before January 1, 2013. This rule applies within three years from the promulgation date of the <u>September 5, 2014</u> amendment to this Regulation. The central health competent authority shall determine or announce whether the medical device applying for registration and market approval requires clinical trials in Taiwan in light of the medical device product item, the case, and the materials submitted. In the event of already a product in the market similar to the medical device applying for registration, except where other regulations apply, the documents specified in Subparagraphs 10 and 11 of Paragraph 1 may be waived. However, the applicant shall additionally attach a domestic clinical trial report when clinical trials in Taiwan are required in accordance with the fore-	2.The medical device was regulated as a pharmaceutical product before January 1, 2013. This rule applies within three years from the promulgation date of the September 5, 2014 amendment to this Regulation. The central health competent authority shall determine or announce whether the medical device applying for registration and market approval requires clinical trials in Taiwan in light of the medical device product item, the case, and the materials submitted. In the event of already a product in the market similar to the medical device applying for registration, except where other regulations apply, the documents specified in Subparagraphs 10 and 11 of Paragraph 1 may be waived. However, the applicant shall additionally attach a domestic clinical trial report when clinical trials in Taiwan are required in accordance with the fore-	

Amended Provisions	Existing Provisions	Explanations
going Paragraph. In the event of applying for registration and market approval of Class 2 medical devices with no predicate product previously approved to market by the central health competent authority, the documents specified in Subparagraphs 11 of Paragraph 1 may be waived if the medical device is in conformity with the related simplified rules or regulations announced by the central health competent authority. However, a domestic clinical trial report shall be submitted when a domestic clinical trial is required according to Paragraph 3. The registration and market approval of IVDs shall be in conformity with the preceding five paragraphs and announcements by the central health competent authority. For the IVDs listed as Class III according to the Regulations for Governing the Management of Medical Device and required to undergo	going Paragraph. In the event of applying for registration and market approval of Class 2 medical devices with no predicate product previously approved to market by the central health competent authority, the documents specified in Subparagraphs 11 of Paragraph 1 may be waived if the medical device is in conformity with the related simplified rules or regulations announced by the central health competent authority. However, a domestic clinical trial report shall be submitted when a domestic clinical trial is required according to Paragraph 3. IVD applying for registration and market approval shall be in conformity with the preceding five paragraphs and proclamations by the central health competent authority; IVDs listed as Class III according to the Regulations for Governing the Management of Medical Device and announced as the item re-	

Amended Provisions	Existing Provisions	Explanations
testing, as announced by the central health competent authority, two (2) copies of the documents specified in Subparagraph 8 of Paragraph 1 shall be submitted, and submission for testing is required. The Class III medical device applying for registration and market approval, shall submit documents of Essential Principles (EP) and Summary of Technical Documentation (STED) in accordance with Appendix. In the event of the medical device applying for registration is commissioned to manufacture or analysis, in addition to conformity with the preceding seven paragraphs, conformity with the Regulations for Medicament Contract Manufacture and Analysis shall also be required. The medical device applying for registration according to the Paragraph 1 shall be in conformity with related rules or regulations announced by the central health	quired testing by the central health competent authority shall also submit for testing. The Class III medical device applying for registration and market approval, shall submit documents of Essential Principles (EP) and Summary of Technical Documentation (STED) in accordance with Appendix. In the event of the medical device applying for registration is commissioned to manufacture or analysis, in addition to conformity with the preceding seven paragraphs, conformity with the Regulations for Medicament Contract Manufacture and Analysis shall also be required. The medical device applying for registration according to the Paragraph 1 shall be in conformity with related rules or regulations announced by the central health competent authority; document exempted from submission shall be kept at the manufacturing factory for possible in-	

Amended Provisions	Existing Provisions	Explanations
competent authority; document exempted from submission shall be kept at the manufacturing factory for possible inspection, The medical device applying for registration and market approval in the Paragraph 1 shall be in conformity with related rules or regulations announced by the central health competent authority, and documents exempted from submission shall be kept. The central health competent authority may order its submission when necessary.	spection, The medical device applying for registration and market approval in the Paragraph 1 shall be in conformity with related rules or regulations announced by the central health competent authority, and documents exempted from submission shall be kept. The central health competent authority may order its submission when necessary.	
Article 24 The following documents shall be attached when applying for change of the specifications on a medical device permit license: 1.Application form for change in medical device permit license. 2.Original copy of the medical device permit license. 3.Original copy of the already approved instruction leaflet stamped with tally impression of the central	Article 24 The following documents shall be attached when applying for change of the specifications on a medical device permit license: 1.Application form for change in medical device permit license. 2.Original copy of the medical device permit license. 3.Original copy of the already approved instruction leaflet stamped with tally impression of the central	1. Subparagraph 7 of Paragraph 1 is amended. Any change in the specifications of a medical device (such as new availability of contact lenses in different diameters or colors) shall be done after evaluated by the original designer or manufacturer of the product, so as to ensure the safety and efficacy of the product. Therefore, the amendment requires that the comparison and explanation of the

Amended Provisions	Existing Provisions	Explanations
health competent authority. 4.Two copies of each of the following items: the affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, labels and color pictures of the physical appearance of product. 5.One copy of each of the following items: pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer. 6.One copy of each of the relevant documents concerning product structure, materials, specifications, performance, intended uses, and drawings, etc. For instrument product, an operation manual or a service manual covers all of the abovementioned items may be a substitution. 7.<u>The original copy of</u> the	health competent authority. 4.Two copies of each of the following items: the affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, labels and color pictures of the physical appearance of product. 5.One copy of each of the following items: pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer. 6.One copy of each of the relevant documents concerning product structure, materials, specifications, performance, intended uses, and drawings, etc. For instrument product, an operation manual or a service manual covers all of the abovementioned items may be a substitution. 7.A comparison table of	changed specifications and the originally approved specifications submitted for the purpose of applying for change of the specifications on a permit license shall be issued by the original medical device manufacturer. 2. The text in Paragraph 3 is slightly amended. The previous provisions stipulate that for Class III IVDs, compliance with the preceding two paragraphs is required, and an original covering letter issued by the original manufacturer shall be submitted. When necessary, stability test results and other relevant data shall also be provided. However, “stability test results and other relevant data” are part of “pre-clinical testing” set forth in Subparagraph 5 of Paragraph 1. The “original manufacturer’s covering letter” is a redundancy of the “original copy of the comparison and explanation of the changed specifications and the originally approved specifications

Amended Provisions	Existing Provisions	Explanations
comparison and explanation of the changed specifications and the originally approved specifications issued by the original manufacturer; 8.The original copy of the manufacture and free sale certificate of the country of origin. 9.The original copy of foreign original manufacturer authorization letter. 10.Two copies of radiation safety information for equipment generating ionizing radiation. The documents in The documents in Subparagraphs 8 and 9 of the foregoing Paragraph may be waived when applying to change a domestically-manufactured medical device permit license. The application for change of the specifications of a medical device shall be in conformity with the preceding two paragraphs if such a device is a Class III IVD. Moreover, if the IVD is required to undergo testing, as announced by the	the change and the original specification with explanation. 8.The original copy of the manufacture and free sale certificate of the country of origin. 9.The original copy of foreign original manufacturer authorization letter. 10.Two copies of radiation safety information for equipment generating ionizing radiation. The documents in Subparagraphs 8 and 9 of the foregoing Paragraph may be waived when applying to change a domestically-manufactured medical device permit license. When the medical device for which an application to add specifications has been made is a Class III IVD, in addition to the preceding two paragraphs, original copy of the original manufacturer covering letter shall be submitted, when necessary, attach stability test results and other relevant data; when the type of device is announced as	issued by the original manufacturer" set forth in the amended Subparagraph 7 of Paragraph 1. Thus, said text is deleted. Moreover, for medical devices that are required to undergo testing, two (2) copies of the documents stating the test specifications and methods for pre-clinical testing and quality control conducted by the original manufacturer, the original test records, and the test result reports shall be submitted.

Amended Provisions	Existing Provisions	Explanations
central health competent authority, two (2) copies of the documents specified in Subparagraph 5 of Paragraph 1 shall be submitted, and submission for testing is required. The medical device applying for registration in Paragraph 1 shall be in conformity with related rules or regulations announced by the central health competent authority, and the documents exempted from submission shall be kept in the manufacturing factory. The central health competent authority may order its submission when necessary.	the one required testing by the central health competent authority shall also submit for testing. The medical device applying for registration in Paragraph 1 shall be in conformity with related rules or regulations announced by the central health competent authority, and the documents exempted from submission shall be kept in the manufacturing factory. The central health competent authority may order its submission when necessary.	
Article 26 The following documents shall be attached when applying for change in medical device efficacy, indication, performance, instruction for use, or dosage on a medical device permit, the following documents shall be submitted: 1.Application form for change in medical device permit license. 2.Original copy of the	Article 26 The following documents shall be attached when applying for change in medical device efficacy, indication, performance, instruction for use, or dosage on a medical device permit, the following documents shall be submitted: 1.Application form for change in medical device permit license. 2.Original copy of the	Subparagraph 11 of Paragraph 1 is added. Any change in the efficacy of a medical device (for example, the graft materials previously for dental purposes only may also be used for other bone defects) shall be done after evaluated by the original designer or manufacturer of the product, so as to ensure the safety and efficacy of the product. Therefore, the

Amended Provisions	Existing Provisions	Explanations
medical device permit license. 3.Original copy of the already approved instruction leaflet stamped with tally impression of the central health competent authority. 4.Two copies of each of the following items: the affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, labels and color pictures of the physical appearance of product. 5.One copy of the following items: pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer. 6.One copy of each of the relevant documents concerning product structure, materials, specifications, functions, intended uses, and drawings, etc. For	medical device permit license. 3.Original copy of the already approved instruction leaflet stamped with tally impression of the central health competent authority. 4.Two copies of each of the following items: the affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, labels and color pictures of the physical appearance of product. 5.One copy of the following items: pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer. 6.One copy of each of the relevant documents concerning product structure, materials, specifications, functions, intended uses, and drawings, etc. For	comparison and explanation of the changed efficacy and the originally approved efficacy submitted for the purpose of applying for change of the efficacy on a permit license shall be issued by the original medical device manufacturer.

Amended Provisions	Existing Provisions	Explanations
instrument product, an operation manual or a service manual covers all of the abovementioned items may be a substitution. 7.The original copy of the manufacture and free sale certificate of the country of origin. 8.The original copy of foreign original manufacturer authorization letter. 9.Theoretical basis and relevant research reports and data. 10.Clinical trial reports. 11. The original copy of the comparison and explanation of the changed particulars and the originally approved particulars issued by the original manufacturer. In the event of applying for change of a domestically manufactured medical device, Subparagraph 7 and 8 and of the preceding paragraph shall be exempted. In the event of already a product in the market similar to the medical device applying	instrument product, an operation manual or a service manual covers all of the abovementioned items may be a substitution. 7.The original copy of the manufacture and free sale certificate of the country of origin. 8.The original copy of foreign original manufacturer authorization letter. 9.Theoretical basis and relevant research reports and data. 10.Clinical trial reports. In the event of applying for change of a domestically manufactured medical device, Subparagraph 7 and 8 and of the preceding paragraph shall be exempted. In the event of already a product in the market similar to the medical device applying for changes of Paragraph 1, the documents specified in Subparagraphs 9 and 10 of Paragraph 1 may be waived. The medical device applying for registration in Paragraph 1 and Para-	

Amended Provisions	Existing Provisions	Explanations
for changes of Paragraph 1, the documents specified in Subparagraphs 9 and 10 of Paragraph 1 may be waived. The medical device applying for registration in Paragraph 1 and Paragraph 3 shall be in conformity with related rules or regulations announced by the central health competent authority, and the documents exempted from submission shall be kept in the manufacturing factory. The central health competent authority may order its submission when necessary.	graph 3 shall be in conformity with related rules or regulations announced by the central health competent authority, and the documents exempted from submission shall be kept in the manufacturing factory. The central health competent authority may order its submission when necessary.	
Article 28 The following documents shall be attached when applying for change in address of manufacturing factory (including the country of origin): 1.Application form for change in medical device permit license. 2.Original copy of the medical device permit license. 3.Original manufacturer covering letter that explains the change in manufacturing factory	Article 28 The following documents shall be attached when applying for change in address of manufacturing factory (including the country of origin): 1.Application form for change in medical device permit license. 2.Original copy of the medical device permit license. 3.Original manufacturer covering letter that explains the change in manufacturing factory	1. Paragraph 5 is amended. For the change of the address of the manufacturing factory of Class III IVDs, documents regarding pre-clinical testing and quality control conducted by the original manufacturer are required in accordance with Article 12, to verify the safety and functionality of the products. Therefore, new contents are added to the original provisions to avoid any doubts during reviews

Amended Provisions	Existing Provisions	Explanations
address. 4.Photocopy of pharmaceutical firm permit license of the manufacturing factory with the new address. 5.Original copy of the manufacture and free sale certificate of the country of origin. 6.The original copy of foreign original manufacturer authorization letter. 7.Documents verifying that the manufacturing factory in conformity with the GMP for Medical Devices. In the event of applying for change in manufacturing factory name for an imported medical device, Subparagraph 4 of the preceding paragraph shall be exempted. In the event of applying for change in manufacturing factory name for a domestically manufactured medical device, Subparagraph 5 and 6 of Paragraph 1 shall be exempted. If change of the manufacturing factory address was due to	address. 4.Photocopy of pharmaceutical firm permit license of the manufacturing factory with the new address. 5.Original copy of the manufacture and free sale certificate of the country of origin. 6.The original copy of foreign original manufacturer authorization letter. 7.Documents verifying that the manufacturing factory in conformity with the GMP for Medical Devices. In the event of applying for change in manufacturing factory name for an imported medical device, Subparagraph 4 of the preceding paragraph shall be exempted. In the event of applying for change in manufacturing factory name for a domestically manufactured medical device, Subparagraph 5 and 6 of Paragraph 1 shall be exempted. If change of the manufacturing factory address was due to	and be consistent with the current review requirements. 2. Paragraph 6 is added. To prevent the change of the address of a medical device manufacturing factory from resulting in any inconsistency with its medical device previously approved for registration and market approval in terms of the quality, safety, and efficacy, the central health competent authority may order the applicant to submit documents regarding preclinical testing and quality control conducted by the original manufacturer to verify the safety and functionality of the product.

Amended Provisions	Existing Provisions	Explanations
house-numbering system change, document for Subparagraph 5 of Paragraph 1 may be exempted, a certificate issued by government shall be submitted; in the case of imported medical devices, the certificate shall be notarized by R.O.C (Taiwan) foreign affairs office. In the case of a Class III IVD, the application for change shall be in conformity with the preceding four paragraphs. Moreover, two (2) copies of the documents stating the test specifications and methods for pre-clinical testing and quality control conducted by the original manufacturer, the original test records, and the test result reports shall be submitted. If the IVD is required to undergo testing, as announced by the central health competent authority, submission for testing is also required. For medical devices for which an application for change of the address of the manufacturing factory is submitted in	house-numbering system change, document for Subparagraph 5 of Paragraph 1 may be exempted, a certificate issued by government shall be submitted; in the case of imported medical devices, the certificate shall be notarized by R.O.C (Taiwan) foreign affairs office. When the medical device for which an application to change manufacturing factory address has been made is a Class III IVD, in addition to the preceding 4 paragraphs, two copy of each of the following items, including pre-clinical testing and the test specifications and methods, the original test records, and the test reports of the quality control conducted by the original manufacturer, shall be submitted. When the type of device is announced as the one required testing by the central health competent authority, the applicant shall also submit for testing.	

Amended Provisions	Existing Provisions	Explanations
accordance with Paragraph 1, the central health competent authority may, if necessary, order submission of technical documentation such as relevant documents concerning product structure, materials, specifications, performance, intended use, and drawings, pre-clinical testing documents, and test results of quality control by the original manufacturer.		
Article 35 The following documents shall be attached when applying for extension of the validity period of a medical device permit license: 1.A medical device permit license validity period extension application form approved by the special municipality, county and city health competent authority of the pharmaceutical company's locality. 2.Original copy of the medical device permit license. 3.The original copy of the manufacture and free sale certificate of the	Article 35 The following documents shall be attached when applying for extension of the validity period of a medical device permit license: 1.A medical device permit license validity period extension application form approved by the special municipality, county and city health competent authority of the pharmaceutical company's locality. 2.Original copy of the medical device permit license. 3.The original copy of the manufacture and free sale certificate of the	1. Paragraph 4 is added. To strengthen the management of Class I medical devices, the uploading of the instructions, labels, and outer boxes of Class I medical devices has become a requirement for applying for extension. 2. The text in Subparagraph 2 of Paragraph 6 is amended. 3. Paragraph 7 is added. If there are doubts about the safety and efficacy of the product concerned by the application for extension, the central health competent authority may order the manufacturer to submit

Amended Provisions	Existing Provisions	Explanations
country of origin. 4.Original copy of foreign original manufacturer continual authorization letter. 5.Certificate of in conformity with the GMP for Medical Devices. Product items in accordance with the Article 4 Appendix II of the Regulations for Governing the Management of Medical Device are exempted from this subparagraph. The medical device applying for foregoing paragraph application is commissioned to manufacture or analysis, it shall be in conformity with the Regulations for Medicament Contract Manufacture and Analysis. In the event of applying for extension of the validity period of a medical device permit license for a domestically manufactured medical device, the applicant is exempted from submitting documents specified in Subparagraph 3 and 4 of Paragraph 1. <u>In the event of ap-</u>	country of origin. 4.Original copy of foreign original manufacturer continual authorization letter. 5.Certificate of in conformity with the GMP for Medical Devices. Product items in accordance with the Article 4 Appendix II of the Regulations for Governing the Management of Medical Device are exempted from this subparagraph. The medical device applying for foregoing paragraph application is commissioned to manufacture or analysis, it shall be in conformity with the Regulations for Medicament Contract Manufacture and Analysis. In the event of applying for extension of the validity period of a medical device permit license for a domestically manufactured medical device, the applicant is exempted from submitting documents specified in Subparagraph 3 and 4 of Paragraph 1. In the event of ap-	relevant documents, so as to ensure the efficacy and safety of the product.

Amended Provisions	Existing Provisions	Explanations
plying for extension of a Class I medical device permit license, this article shall apply, and the instructions, labels, and outer box shall first be uploaded to the information system specified by the central health competent authority. In the event of applying extension of the validity period of a medical device permit license of a Class I medical device, in addition to complying this article, Articles 14 and 16 shall be applied mutatis mutandis. If meeting one of the following circumstances, documents of the Subparagraphs 5 in the Paragraph 1 may be substituted with photocopies of documents verifying compliance with GMP for Pharmaceuticals: 1.The medical device applying for registration was regulated as a pharmaceutical product before. This rule applies within three years from the date of proclamations of listing change. 2.The medical device was	plying extension of the validity period of a medical device permit license of a Class I medical device, in addition to complying this article, Articles 14 and 16 shall be applied mutatis mutandis. If meeting one of the following circumstances, documents of the Subparagraphs 5 in the Paragraph 1 may be substituted with photocopies of documents verifying compliance with GMP for Pharmaceuticals: 1.The medical device applying for registration was regulated as a pharmaceutical product before. This rule applies within three years from the date of proclamations of listing change. 2.The medical device was regulated as a pharmaceutical product before January 1, 2013. This rule applies within three years from the promulgation date of the September 5, 2014 amendment to this Regulation. The manufacturing factory with valid medical device li-	

Amended Provisions	Existing Provisions	Explanations
regulated as a pharmaceutical product before January 1, 2013. This rule applies within three years from the promulgation date of the September 5, 2014 amendment to this Regulation. The manufacturing factory with valid medical device license shall not be approved for extension if it fails to conform to the GMP for medical device. For the application for extension of a permit license in accordance with Paragraph 1, the central health competent authority may order submission of relevant documents if there are doubts about the safety and efficacy of the product concerned.	cense shall not be approved for extension if it fails to conform to the GMP for medical device.	
Article 36 Publication of medical device instruction leaflet, labeling and packaging, in addition to conformity with Article 75 of the Act and related proclamations made by the central health competent authority, applicant shall modify, supplement or resend related docu-	Article 36 Publication of medical device instruction leaflet, labeling and packaging, in addition to conformity with Article 75 of the Act and related proclamations made by the central health competent authority, applicant shall modify, supplement or resend related docu-	Paragraphs 5 and 6 are added. To collect complete information on the instructions of Class I medical devices and improve the management after launch to the market, permit license holders are required to upload the instructions, labels, and outer box documents to the infor-

Amended Provisions	Existing Provisions	Explanations
ments under the request of central health competent authority. Medical device instruction leaflet shall publicize all contraindication, warning, side effects, and other notices, in red, red box, or bold type fonts. Font type in a Chinese instruction leaflet shall not be smaller than 7-pt font. Domestic medical device labeling, instruction leaflet, and packaging shall mainly publicize in Chinese characters. Characters in any other language shall be smaller than Chinese ones. For imported medical device, in addition to mandatary Chinese instruction leaflet, labeling and packaging shall publicize product name, medical device permit license number, the name and address of the pharmaceutical firm as the importer shall all be in Chinese characters. Manufacturing date and expiration date shall be in Chinese characters as well, or understood habitually;	ments under the request of central health competent authority. Medical device instruction leaflet shall publicize all contraindication, warning, side effects, and other notices, in red, red box, or bold type fonts. Font type in a Chinese instruction leaflet shall not be smaller than 7-pt font. Domestic medical device labeling, instruction leaflet, and packaging shall mainly publicize in Chinese characters. Characters in any other language shall be smaller than Chinese ones. For imported medical device, in addition to mandatary Chinese instruction leaflet, labeling and packaging shall publicize product name, medical device permit license number, the name and address of the pharmaceutical firm as the importer shall all be in Chinese characters. Manufacturing date and expiration date shall be in Chinese characters as well, or understood habitually;	mation system specified by the central health competent authority within one (1) month after obtaining permit licenses or within six (6) months from the date of promulgation of the Amendment to this Regulation if they have obtained permit licenses.

Amended Provisions	Existing Provisions	Explanations
Characters in any other language shall be smaller than Chinese ones. Holders of permit licenses for approved and launched Class I medical devices shall, within one (1) month after obtaining the permit licenses, upload the instructions, labels, and outer boxes to the information system specified by the central health competent authority. Permit license holders shall assume the obligations to ensure the authenticity of all uploaded contents, including the names of the uploaded documents, labels, instructions, packaging, trademarks, and drawings. Permit license holders who obtain Class I medical device permit licenses before the amendment to this Regulation comes into force shall, within six (6) months from the date of promulgation of the ○○○ Amendment to this Regulation, upload the instructions, labels, and outer boxes in accordance with	Characters in any other language shall be smaller than Chinese ones.	

Amended Provisions	Existing Provisions	Explanations
the preceding paragraph.		
Article 37 The product name of a medical device shall comply with the following regulations: 1.A product name shall not use pharmaceutical name, trademark, or name of manufacturer from others, unless trademark awarded or authorization obtained. 2.A product name shall not be the same as other medical device, or involved in counterfeiting or insinuation. 3.Product name shall not involve in misrepresentation, overstatement, or leading people in improper association with medical device and/or efficacy. 4.Chinese product name shall not contain any character in any other language or in numbers, unless phrases used contain meaning directly related, or English trademarks contains special meaning and approved by the central health competent authority. 5.The Chinese and English	Article 37 The product name of a medical device shall comply with the following regulations: 1.A product name shall not use pharmaceutical name, trademark, or name of manufacturer from others, unless trademark awarded or authorization obtained. 2.A product name shall not be the same as other medical device, or involved in counterfeiting or insinuation. 3.Product name shall not involve in misrepresentation, overstatement, or leading people in improper association with medical device and/or efficacy. 4.Chinese product name shall not contain any character in any other language or in numbers, unless phrases used contain meaning directly related, or English trademarks contains special meaning and approved by the central health competent authority. 5.A product name shall	Subparagraph 5 of Paragraph 1 is added. Since the review process for medical devices exclusively for export is different from that for domestically manufactured medical devices, it is explicitly stipulated that the Chinese and English names of medical devices exclusively for export shall not be the same as those of domestically manufactured medical devices. Thus, any confusion between medical devices exclusively for export and domestically manufactured medical devices can be avoided.

Amended Provisions	Existing Provisions	Explanations
names of medical devices exclusively for export shall not be the same as those of domestically manufactured medical devices. 6. A product name shall not be in other improper situations as a name of medical device. The precedence of medical device names that are identical or similar shall be determined on the basis of the precedence of trademarks, company names, or other identifiable names. The central health competent authority may review the name of a medical device already approved for sale in accordance with regulations of the foregoing two paragraphs.	not be in other improper situations as a name of medical device. The precedence of medical device names that are identical or similar shall be determined on the basis of the precedence of trademarks, company names, or other identifiable names. The central health competent authority may review the name of a medical device already approved for sale in accordance with regulations of the foregoing two paragraphs.	