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 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

Existing Provisions

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.

Explanations

- 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.
- 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.

	T	
Amended Provisions	Existing Provisions	Explanations
with this Regulation are		
not in Traditional Chinese		
or English, a Traditional		
Chinese or English trans-		
lation shall be provided.		
Article 7 The manufacture	Article 7 The manufacture	Paragraph 3 is amended.
and free sale certificates	and free sale certificates	The current relationship
of the country of origin	of the country of origin	between the commissioning
referred to in this Regula-	referred to in this Regula-	company and the commis-
tion are verifying docu-	tion are verifying docu-	sioned manufacturing
ments issued by the high-	ments issued by the high-	factory is proved by a
est health authority of	est health authority of	commissioning contract.
the country where the	the country where the	Thus, "the documents shall
imported medical device	imported medical device	provide clear description
is manufactured. The	is manufactured. The	about the relationship
content of such docu-	content of such docu-	between the commissioning
ments shall state the	ments shall state the	company and commissioned
name and the address of	name and the address of	manufacturing factory" is
the manufacturing facto-	the manufacturing facto-	deleted.
ry, the name of the medi-	ry, the name of the medi-	
cal device, the specifica-	cal device, the specifica-	
tions and model of the	tions and model of the	
medical device, the cir-	medical device, the cir-	
cumstances of manufac-	cumstances of manufac-	
ture, and the certification	ture, and the certification	
of approval for domestic	of approval for domestic	
sale in that country. If it is	sale in that country. If it is	
confirmed that the medi-	confirmed that the medi-	
cal device is not regulated	cal device is not regulated	
by the highest health	by the highest health	
authority in the country	authority in the country	
of the manufacturer, said	of the manufacturer, said	
manufacturing and sales	manufacturing and sales	
approval documents may	approval documents may	
be issued by the local	be issued by the local	
health agency or an or-	health agency or an or-	
ganization approved by	ganization approved by	

Amended Provisions	Existing Provisions	Explanations
Taiwan's central health	Taiwan's central health	
competent authority.	competent authority.	
With regard to the	With regard to the	
manufacture and free	manufacture and free	
sale certificates in the	sale certificates in the	
foregoing Paragraph, if an	foregoing Paragraph, if an	
imported medical device	imported medical device	
is commissioned to man-	is commissioned to man-	
ufacture, and the device	ufacture, and the device	
is not on sale in the coun-	is not on sale in the coun-	
try of the commissioned	try of the commissioned	
manufacturing factory, a	manufacturing factory, a	
free sale certificate issued	free sale certificate issued	
from the country's high-	from the country's high-	
est competent health	est competent health	
authority of the commis-	authority of the commis-	
sioning company and a	sioning company and a	
manufacture certificate	manufacture certificate	
issued from the country's	issued from the country's	
competent authority of	competent authority of	
commissioned manufac-	commissioned manufac-	
turing factory may be	turing factory may be	
submitted instead of the	submitted instead of the	
foregoing manufacture	foregoing manufacture	
and free sale certificate.	and free sale certificate.	
If an imported medi-	If an imported medi-	
cal device is commis-	cal device is commis-	
sioned to be manufac-	sioned to be manufac-	
tured, the manufacture	tured, the manufacture	
and free sale certificates	and free sale certificates	
in Paragraph 1 are al-	in Paragraph 1 are al-	
lowed to be issued by	lowed to be issued by	
respective highest health	respective highest health	
competent authority of	competent authority of	
the country either of the	the country either of the	
commissioning company	commissioning company	
or of the commissioned	or of the commissioned	

Amended Provisions	Existing Provisions	Explanations
manufacturing factory.	manufacturing factory.	
The manufacture	The documents shall	
and free sale certificates	provide clear description	
in Paragraph 1 is allowed	about the relationship	
to be substituted by a	between the commission-	
certificate of manufacture	ing company and com-	
issued by the government	missioned manufacturing	
of the country where the	<u>factory.</u>	
imported medical device	The manufacture and	
is manufactured and a	free sale certificates in	
certificate of free sale	Paragraph 1 is allowed to	
issued by the highest	be substituted by a certif-	
health competent author-	icate of manufacture	
ity of the United States of	issued by the government	
America, or any member	of the country where the	
state of the European	imported medical device	
Union.	is manufactured and a	
The verifying docu-	certificate of free sale	
ments in the four preced-	issued by the highest	
ing paragraphs shall re-	health competent author-	
main valid for two years	ity of the United States of	
after the date of issuance,	America, or any member	
and shall be notarized by	state of the European	
Taiwan's embassy or con-	Union.	
sulate, representative	The verifying docu-	
office, other official of-	ments in the four preced-	
fice, or overseas organiza-	ing paragraphs shall re-	
tion in that country au-	main valid for two years	
thorized by the Ministry	after the date of issuance,	
of Foreign Affairs (hereaf-	and shall be notarized by	
ter referred to as the	Taiwan's embassy or con-	
overseas representative	sulate, representative	
organization of Taiwan). A	office, other official office,	
Chinese or English trans-	or overseas organization	
lation shall be attached	in that country authorized	
when the verifying doc-	by the Ministry of Foreign	

Affairs (hereafter referred

uments are not in English,

Amended Provisions	Existing Provisions	Explanations
and the translation shall	to as the overseas repre-	
also be notarized.	sentative 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	Article 14 For application	Paragraph 5 is added.
of registration and market	of registration and market	Online application becomes
approval of domestically	approval of domestically	available to meet the needs
manufactured Class 1	manufactured Class 1	for e-government. In
medical devices, the fol-	medical devices, the fol-	addition, it is explicitly
lowing documents shall	lowing documents shall	stated that the applicant
be submitted for review:	be submitted for review:	shall sign or affix their seal if
1. Application form for	1. Application form for	an application is submitted
Class 1 medical device	Class 1 medical device	in writing. If a registration
registration and market	registration and market	application is submitted
approval and original	approval and original	online, the identity of the
copy of affidavit.	copy of affidavit.	applicant must be con-
2.A photocopy of pharma-	2.A photocopy of pharma-	firmed by means of elec-
ceutical firm permit li-	ceutical firm permit li-	tronic signature since the
cense as a medical de-	cense as a medical de-	applicant is unable to sign
vice manufacturer.	vice manufacturer.	or affix their seal. As a
3.Documents verifying	3.Documents verifying	result, the latter part of the
that the manufactory in	that the manufactory in	paragraph explicitly stipu-
conformity with the	conformity with the	lates that those submitting
Good Manufacturing	Good Manufacturing	an application online shall
Practices for Medical	Practices for Medical	do so with the IC card
Devices in accordance	Devices in accordance	issued by the Certificate
with the Part 3 of the	with the Part 3 of the	Authority of the Ministry of
Pharmaceutical Good	Pharmaceutical Good	Economic Affairs. Moreover,
Manufacturing Practice	Manufacturing Practice	the pharmaceutical firm
Regulations (hereafter	Regulations (hereafter	permit licenses of those
referred to as GMP for	referred to as GMP for	submitting an application
Medical Devices). Prod-	Medical Devices). Prod-	online may be inspected on

Amended Provisions	Existing Provisions	Explanations
uct items in accordance	uct items in accordance	the system. Therefore, the
with the Article 4 Ap-	with the Article 4 Ap-	applying pharmaceutical
pendix II of the Regula-	pendix II of the Regula-	firms are not required to
tions for Governing the	tions for Governing the	provide said documents.
Management of Medical	Management of Medical	
Device are exempted	Device are exempted	
from this subparagraph.	from this subparagraph.	
In the event of the	In the event of the	
pharmaceutical firm ap-	pharmaceutical firm ap-	
plying for registration	plying for registration	
different from the manu-	different from the manu-	
facturer, it shall be	facturer, it shall be	
deemed as commission	deemed as commission	
manufacturing.	manufacturing.	
The medical device	The medical device	
applying for registration is	applying for registration is	
commissioned to manu-	commissioned to manu-	
facture or analysis, it shall	facture or analysis, it shall	
be in conformity with the	be in conformity with the	
Regulations for Medica-	Regulations for Medica-	
ment Contract Manufac-	ment Contract Manufac-	
ture and Analysis.	ture and Analysis.	
The medical device	The medical device	
applying for registration	applying for registration in	
in Paragraph 1 shall be in	Paragraph 1 shall be in	
conformity with procla-	conformity with proclama-	
mations of the central	tions of the central health	
health competent author-	competent authority; and	
ity; and the technical	the technical documenta-	
documentation of the	tion of the device shall be	
device shall be kept in the	kept in the manufactory	
manufactory for inspec-	for inspection, which	
tion, which including: the	including: the Chinese	
Chinese instruction leaf-	instruction leaflet, instruc-	
let, instruction for use,	tion for use, packaging,	
packaging, labels of the	labels of the medical	

device, and documents

medical device, and doc-

Amended Provisions	Evicting Provisions	Evaluations
	Existing Provisions with the product infor-	Explanations
uments with the product information such as con-	mation such as construc-	
struction, material, speci-	tion, material, specifica-	
fication, efficacy, purpose,	tion, efficacy, purpose,	
drawing and others, and	drawing and others, and	
documents of pre-clinical	documents of pre-clinical	
trial, and inspection re-	trial, and inspection re-	
sults of quality control of	sults of quality control of	
original manufacturer.	original manufacturer. The	
The central health com-	central health competent	
petent authority may	authority may order its	
order its submission if	submission if necessary.	
necessary.		
The registration and		
market approval applica-		
tion 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 applica-		
tion form. In the case of		
submission online, the IC		
card issued by the Certifi-		
cate 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 15 For application	Article 15 For application	1. The text in Subparagraph
of registration and market	of registration and market	2 of Paragraph 2 is
approval for domestically	approval for domestically	amended. 2. Paragraph 7 is amended.
manufactured Class 2 or	manufactured Class 2 or	For medical devices that

Amended Provisions	Existing Provisions	Explanations
Class 3 medical devices,	Class 3 medical devices,	require submission for
the following documents	the following documents	testing, two (2) copies of the documents stating
shall be submitted for	shall be submitted for	the test specifications
review:	review:	and methods for pre-
1.One copy each of the	1.One copy each of the	clinical testing and quali-
original and photocopy	original and photocopy	ty control conducted by the original manufactur-
of the medical device	of the medical device	er, the original test rec-
registration and market	registration and market	ords, and the test result
approval application	approval application	reports shall be submit-
form.	form.	ted.
2.Two copies of each of	2.Two copies of each of	
the following items: the	the following items: the	
form for attaching outer	form for attaching outer	
box instruction label	box instruction label	
with all Chinese instruc-	with all Chinese instruc-	
tion leaflet catalog	tion leaflet catalog	
packaging, and labeling,	packaging, and labeling,	
instructions for use, and	instructions for use, and	
color pictures of the	color pictures of the	
physical appearance of	physical appearance of	
product.	product.	
3.A photocopy of pharma-	3.A photocopy of pharma-	
ceutical firm permit li-	ceutical firm permit li-	
cense as a medical de-	cense as a medical de-	
vice manufacturer.	vice manufacturer.	
4.Affidavit (A)	4.Affidavit (A)	
5.Documents verifying	5.Documents verifying	
that the domestic man-	that the domestic man-	
ufacturing factory is in	ufacturing factory is in	
conformity with the	conformity with the	
GMP for Medical Devic-	GMP for Medical Devic-	
es.	es.	
6.One copy of each of the	6.One copy of each of the	
follwing items: pre-	follwing items: pre-	
clinical testing and the	clinical testing and the	
test specifications and	test specifications and	
methods, the original	methods, the original	

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

Amended Provisions	Existing Provisions	Explanations
the Part 2 of the Pharma-	the Part 2 of the Pharma-	
ceutical Good Manufac-	ceutical Good Manufac-	
turing Practice Regula-	turing Practice Regula-	
tions (hereafter referred	tions (hereafter referred	
to as GMP for Pharma-	to as GMP for Pharma-	
ceuticals):	ceuticals):	
1.The medical device	1.The medical device	
applying for registration	applying for registration	
and market approval	and market approval	
was regulated as phar-	was regulated as phar-	
maceutical product be-	maceutical product be-	
fore. This rule applies	fore. This rule applies	
within three years from	within three years from	
the date of proclama-	the date of proclama-	
tions of listing change.	tions of listing change.	
2.The medical device was	2.The medical device was	
regulated as a pharma-	regulated as a pharma-	
ceutical product before	ceutical product before	
January 1, 2013. This	January 1, 2013. This	
rule applies within three	rule applies within three	
years from the promul-	years from the promul-	
gation date of the Sep-	gation date of the Sep-	
tember 5, 2014	tember 5, 2014	
amendment to this	amendment to this	
Regulation.	Regulation.	
The central health	The central health	
competent authority shall	competent authority shall	
determine or announce	determine or announce	
whether the medical	whether the medical	
device applying for regis-	device applying for regis-	
tration and market ap-	tration and market ap-	
proval requires clinical	proval requires clinical	
trials in Taiwan in light of	trials in Taiwan in light of	
the medical device prod-	the medical device prod-	
uct item, the case, and	uct item, the case, and	
the materials submitted.	the materials submitted.	
In the event of al-	In the event of al-	

Amended Provisions	Existing Provisions	Explanations
ready a product in the	ready a product in the	
market similar to the	market similar to the	
medical device applying	medical device applying	
for registration, except	for registration, except	
where other regulations	where other regulations	
apply, the documents	apply, the documents	
specified in Subpara-	specified in Subpara-	
graphs 8 and 9 of Para-	graphs 8 and 9 of Para-	
graph 1 may be waived.	graph 1 may be waived.	
However, the applicant	However, the applicant	
shall additionally attach a	shall additionally attach a	
domestic clinical trial	domestic clinical trial	
report when clinical trials	report when clinical trials	
in Taiwan are required in	in Taiwan are required in	
accordance with the fore-	accordance with the fore-	
going Paragraph.	going Paragraph.	
In the event of ap-	In the event of ap-	
plying for registration and	plying for registration and	
market approval of Class	market approval of Class	
2 medical devices with no	2 medical devices with no	
predicate product previ-	predicate product previ-	
ously approved to market	ously approved to market	
by the central health	by the central health	
competent authority, the	competent authority, the	
documents specified in	documents specified in	
Subparagraphs 9 of Para-	Subparagraphs 9 of Para-	
graph 1 may be waived if	graph 1 may be waived if	
the medical device is in	the medical device is in	
conformity with the re-	conformity with the re-	
lated simplified rules or	lated simplified rules or	
regulations announced by	regulations announced by	
the central health compe-	the central health compe-	
tent authority. However, a	tent authority. However, a	
domestic clinical trial	domestic clinical trial	
report shall be submitted	report shall be submitted	
when a domestic clinical	when a domestic clinical	

trial is required according

trial is required according

Amended Provisions	Existing Provisions	Explanations
to Paragraph 3.	to Paragraph 3.	
In the event of ap-	In the event of ap-	
plying for registration of	plying for registration of	
medical devices exclusive-	medical devices exclusive-	
ly for export, submissions	ly for export, submissions	
for testing are not re-	for testing are not re-	
quired, and documents	quired, and documents	
required by Subpara-	required by Subpara-	
graphs 6 to 10 of Para-	graphs 6 to 10 of Para-	
graph 1 shall be exempt-	graph 1 shall be exempt-	
ed.	ed.	
The registration and	IVD applying for reg-	
market approval of IVDs	istration and market ap-	
shall be in conformity	proval shall be in con-	
with the preceding six	formity with the preced-	
paragraphs and an-	ing six paragraphs and	
nouncements by the	proclamations by the	
central health competent	central health competent	
authority. For the IVDs	authority; the IVDs listed	
listed as Class III accord-	as Class III according to	
ing to the Regulations for	the Regulations for Gov-	
Governing the Manage-	erning the Management	
ment of Medical Device	of Medical Device and	
and required to undergo	announced by the central	
testing, as announced by	health competent author-	
the central health compe-	ity for the requirement of	
tent authority, two (2)	testing shall also submit	
copies of the documents	for testing, except prod-	
specified in Subparagraph	ucts exclusively for ex-	
6 of Paragraph 1 shall be	port.	
submitted, and submis-	The medical devices	
sion for testing is re-	applying for Class III regis-	
quired, except for prod-	tration and market ap-	
ucts exclusively for ex-	proval, except products	
port.	exclusively for export,	
The medical devices	shall also submit docu-	

ments of Essential Princi-

applying for Class III regis-

Amended Provisions	Existing Provisions	Explanations
tration and market ap-	ples (EP) and Summary of	
proval, except products	Technical Documentation	
exclusively for export,	(STED) in accordance with	
shall also submit docu-	Appendix.	
ments of Essential Princi-	In the event of the	
ples (EP) and Summary of	pharmaceutical firm ap-	
Technical Documentation	plying for registration and	
(STED) in accordance with	market approval different	
Appendix.	from the manufacturer, it	
In the event of the	shall be deemed as com-	
pharmaceutical firm ap-	mission manufacturing.	
plying for registration and	In the event of the	
market approval different	medical device applying	
from the manufacturer, it	for registration and mar-	
shall be deemed as com-	ket approval is commis-	
mission manufacturing.	sioned to manufacture or	
In the event of the	testing, the device shall	
medical device applying	be in conformity with the	
for registration and mar-	preceding nine para-	
ket approval is commis-	graphs and the Regula-	
sioned to manufacture or	tions for Medicament	
testing, the device shall	Contract Manufacture	
be in conformity with the	and Analysis.	
preceding nine para-	The medical device	
graphs and the Regula-	applying for registration	
tions for Medicament	in Paragraph 1 and Para-	
Contract Manufacture	graph 6 shall be in con-	
and Analysis.	formity with related rules	
The medical device	or regulations announced	
applying for registration	by the central health	
in Paragraph 1 and Para-	competent authority, and	
graph 6 shall be in con-	the documents exempted	
formity with related rules	from submission shall be	
or regulations announced	kept in the manufacturing	
by the central health	factory. The central	
competent authority, and	health competent author-	
the documents exempted	ity may order its submis-	

Amandad Dravisians	Evicting Drovisions	Evalenations
Amended Provisions	Existing Provisions	Explanations
from submission shall be	sion when necessary.	
kept in the manufacturing		
factory. The central		
health competent author-		
ity may order its submis-		
sion when necessary.	A .: 1 46 F 1: .:	
Article 16 For application	Article 16 For application	Paragraph 4 is added.
of registration and market	of registration and market	Online application becomes
approval for imported	approval for imported	available to meet the needs
Class I medical device, the	Class I medical device, the	for e-government. In
following documents shall	following documents shall	addition, it is explicitly
be submitted:	be submitted:	stated that the applicant
1.Application form for	1.Application form for	shall sign or affix their seal if
Class I medical device	Class I medical device	an application is submitted
registration and market	registration and market	in writing. If a registration
approval and original	approval and original	application is submitted
copy of affidavit.	copy of affidavit.	online, the identity of the
2.A photocopy of pharma-	2.A photocopy of pharma-	applicant must be con-
ceutical firm permit li-	ceutical firm permit li-	firmed by means of elec-
cense as a medical de-	cense as a medical de-	tronic signature since the
vice dealer.	vice dealer.	applicant is unable to sign
3.Certificate of in con-	3.Certificate of in con-	or affix their seal. As a
formity with the GMP	formity with the GMP	result, the latter part of the
for Medical Devices.	for Medical Devices.	paragraph explicitly stipu-
Product items in ac-	Product items in ac-	lates that those submitting
cordance with the Arti-	cordance with the Arti-	an application online shall
cle 4 Appendix II of the	cle 4 Appendix II of the	do so with the IC card
Regulations for Govern-	Regulations for Govern-	issued by the Certificate
ing the Management of	ing the Management of	Authority of the Ministry of
Medical Device are ex-	Medical Device are ex-	Economic Affairs.
empted from this sub-	empted from this sub-	
paragraph.	paragraph.	
If the medical device	If the medical device	
applying for registration	applying for registration	
and market approval is	and market approval is	
commissioned to manu-	commissioned to manu-	
facture or analysis, it shall	facture or analysis, it shall	

Amended Provisions	Existing Provisions	Explanations
be in conformity with the	be in conformity with the	
Regulations for Medic-	Regulations for Medic-	
ament Contract Manufac-	ament Contract Manufac-	
ture and Analysis.	ture and Analysis.	
The medical device	The medical device	
applying for registration	applying for registration	
in the Paragraph 1 shall	in the Paragraph 1 shall	
be in conformity with	be in conformity with	
related rules or regula-	related rules or regula-	
tions announced by the	tions announced by the	
central health competent	central health competent	
authority, and the follow-	authority, and the follow-	
ing technical documenta-	ing technical documenta-	
tion of the device shall be	tion of the device shall be	
kept in the manufacturing	kept in the manufacturing	
factory for inspection:	factory for inspection:	
instruction leaflets, the	instruction leaflets, the	
original instruction for	original instruction for	
use with a copy of its	use with a copy of its	
Chinese translation,	Chinese translation,	
packaging, labels of the	packaging, labels of the	
medical device, and doc-	medical device, and doc-	
uments with the infor-	uments with the infor-	
mation of the product	mation of the product	
such as structure, materi-	such as structure, materi-	
als, specifications, per-	als, specifications, per-	
formance, intended use,	formance, intended use,	
drawing and others, and	drawing and others, and	
documents of pre-clinical	documents of pre-clinical	
testing, and the testing	testing, and the testing	
results of quality control	results of quality control	
of the original manufac-	of the original manufac-	
turer. The central health	turer. The central health	
competent authority may	competent authority may	
order its submission	order its submission	
when necessary.	when necessary.	
The registration and		

Amended Provisions	Existing Provisions	Explanations
market approval applica-		
tion 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 Authori-		
ty of the Ministry of Eco-		
nomic Affairs shall be		
used, and the documents		
set forth in Subpara-		
graphs 1 and 2 of Para-		
graph 1 are not required.		
Article 17 For application	Article 17 For application	1. The text in Subparagraph
of registration and market	of registration and market	2 of Paragraph 2 is amended.
approval for imported	approval for imported	2. Paragraph 6 is amended.
Class II or Class III medical	Class II or Class III medical	For medical devices that
devices, the following	devices, the following	require submission for
document shall be sub-	document shall be sub-	testing, two (2) copies of
mitted for review:	mitted for review:	the documents stating the test specifications
1.One copy of each of the	1.One copy of each of the	and methods for pre-
original and photocopy	original and photocopy	clinical testing and quali-
of the medical device	of the medical device	ty control conducted by
registration and market	registration and market	the original manufactur- er, the original test rec-
approval application	approval application	ords, and the test result
form.	form.	reports shall be submit-
2.Two copies of each of	2.Two copies of each of	ted.
the following items: the	the following items: the	
affixed or stapled to the	affixed or stapled to the	
label attachment form	label attachment form	
of instructions and	of instructions and	
manual with detailed	manual with detailed	

Amended Provisions	Existing Provisions	Explanations
Chinese translations,	Chinese translations,	
packaging, labels and	packaging, labels and	
color pictures of the	color pictures of the	
physical appearance of	physical appearance of	
product.	product.	
3.A photocopy of pharma-	3.A photocopy of pharma-	
ceutical firm permit li-	ceutical firm permit li-	
cense as a medical de-	cense as a medical de-	
vice dealer.	vice dealer.	
4.Affidavit (A)	4.Affidavit (A)	
5.The original copy of the	5.The original copy of the	
manufacture and free	manufacture and free	
sale certificate of the	sale certificate of the	
country of origin.	country of origin.	
6.The original copy of the	6.The original copy of the	
foreign original manu-	foreign original manu-	
facturer authorization	facturer authorization	
letter.	letter.	
7.Documents verifying	7.Documents verifying	
that the domestic man-	that the domestic man-	
ufacturing factory in	ufacturing factory in	
conformity with the	conformity with the	
GMP for Medical Devic-	GMP for Medical Devic-	
es.	es.	
8.One copy of each of the	8.One copy of each of the	
following items: pre-	following items: pre-	
clinical testing and the	clinical testing and the	
test specifications and	test specifications and	
methods, the original	methods, the original	
test records, and the	test records, and the	
test reports of the quali-	test reports of the quali-	
ty control conducted by	ty control conducted by	
the original manufac-	the original manufac-	
turer. 9.One copy of each of the	turer. 9.One copy of each of the	
relevant documents	relevant documents	
concerning product	concerning product	
concerning product	concerning product	

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

Amended Provisions	Existing Provisions	Explanations
2.The medical device was	2.The medical device was	
regulated as a pharma-	regulated as a pharma-	
ceutical product before	ceutical product before	
January 1, 2013. This	January 1, 2013. This	
rule applies within three	rule applies within three	
years from the promul-	years from the promul-	
gation date of the <u>Sep-</u>	gation date of the Sep-	
<u>tember 5, 2014</u>	tember 5, 2014	
amendment to this	amendment to this	
Regulation.	Regulation.	
The central health	The central health	
competent authority shall	competent authority shall	
determine or announce	determine or announce	
whether the medical	whether the medical	
device applying for regis-	device applying for regis-	
tration and market ap-	tration and market ap-	
proval requires clinical	proval requires clinical	
trials in Taiwan in light of	trials in Taiwan in light of	
the medical device prod-	the medical device prod-	
uct item, the case, and	uct item, the case, and	
the materials submitted.	the materials submitted.	
In the event of al-	In the event of al-	
ready a product in the	ready a product in the	
market similar to the	market similar to the	
medical device applying	medical device applying	
for registration, except	for registration, except	
where other regulations	where other regulations	
apply, the documents	apply, the documents	
specified in Subpara-	specified in Subpara-	
graphs 10 and 11 of Para-	graphs 10 and 11 of Para-	
graph 1 may be waived.	graph 1 may be waived.	
However, the applicant	However, the applicant	
shall additionally attach a	shall additionally attach a	
domestic clinical trial	domestic clinical trial	
report when clinical trials	report when clinical trials	
in Taiwan are required in	in Taiwan are required in	
accordance with the fore-	accordance with the fore-	

Amended Provisions	Existing Provisions	Explanations
going Paragraph.	going Paragraph.	
In the event of ap-	In the event of ap-	
plying for registration and	plying for registration and	
market approval of Class	market approval of Class	
2 medical devices with no	2 medical devices with no	
predicate product previ-	predicate product previ-	
ously approved to market	ously approved to market	
by the central health	by the central health	
competent authority, the	competent authority, the	
documents specified in	documents specified in	
Subparagraphs 11 of	Subparagraphs 11 of	
Paragraph 1 may be	Paragraph 1 may be	
waived if the medical	waived if the medical	
device is in conformity	device is in conformity	
with the related simpli-	with the related simpli-	
fied rules or regulations	fied rules or regulations	
announced by the central	announced by the central	
health competent author-	health competent author-	
ity. However, a domestic	ity. However, a domestic	
clinical trial report shall	clinical trial report shall	
be submitted when a	be submitted when a	
domestic clinical trial is	domestic clinical trial is	
required according to	required according to	
Paragraph 3.	Paragraph 3.	
The registration and	IVD applying for reg-	
market approval of IVDs	istration and market ap-	
shall be in conformity	proval shall be in con-	
with the preceding five	formity with the preced-	
paragraphs and an-	ing five paragraphs and	
nouncements by the	proclamations by the	
central health competent	central health competent	
authority. For the IVDs	authority; IVDs listed as	
listed as Class III accord-	Class III according to the	
ing to the Regulations for	Regulations for Governing	
Governing the Manage-	the Management of Med-	

nounced as the item re-

and an-

ical Device

ment of Medical Device

and required to undergo

Amended Provisions	Existing Provisions	Explanations
testing, as announced by	quired testing by the	
the central health compe-	central health competent	
tent authority, <u>two (2)</u>	authority shall also sub-	
copies of the documents	mit for testing.	
specified in Subparagraph	The Class III medical	
8 of Paragraph 1 shall be	device applying for regis-	
submitted, and submis-	tration and market ap-	
sion for testing is re-	proval, shall submit doc-	
quired.	uments of Essential Prin-	
The Class III medical	ciples (EP) and Summary	
device applying for regis-	of Technical Documenta-	
tration and market ap-	tion (STED) in accordance	
proval, shall submit doc-	with Appendix.	
uments of Essential Prin-	In the event of the	
ciples (EP) and Summary	medical device applying	
of Technical Documenta-	for registration is com-	
tion (STED) in accordance	missioned to manufac-	
with Appendix.	ture or analysis, in addi-	
In the event of the	tion to conformity with	
medical device applying	the preceding seven par-	
for registration is com-	agraphs, conformity with	
missioned to manufac-	the Regulations for Me-	
ture or analysis, in addi-	dicament Contract Manu-	
tion to conformity with	facture and Analysis shall	
the preceding seven par-	also be required.	
agraphs, conformity with	The medical device	
the Regulations for Me-	applying for registration	
dicament Contract Manu-	according to the Para-	
facture and Analysis shall	graph 1 shall be in con-	
also be required.	formity with related rules	
The medical device	or regulations announced	
applying for registration	by the central health	
according to the Para-	competent authority;	
graph 1 shall be in con-	document exempted	
formity with related rules	from submission shall be	
or regulations announced	kept at the manufacturing	

factory for possible in-

by the central health

A seconded Brancisians	Fuinting Dunctining	F I a satistic and
Amended Provisions	Existing Provisions	Explanations
competent authority;	spection, The medical	
document exempted	device applying for regis-	
from submission shall be	tration and market ap-	
kept at the manufacturing	proval in the Paragraph 1	
factory for possible in-	shall be in conformity	
spection, The medical	with related rules or regu-	
device applying for regis-	lations announced by the	
tration and market ap-	central health competent	
proval in the Paragraph 1	authority, and documents	
shall be in conformity	exempted from submis-	
with related rules or regu-	sion shall be kept. The	
lations announced by the	central health competent	
central health competent	authority may order its	
authority, and documents	submission when neces-	
exempted from submis-	sary.	
sion shall be kept. The		
central health competent		
authority may order its		
submission when neces-		
sary.		
Article 24 The following	Article 24 The following	1. Subparagraph 7 of
documents shall be at-	documents shall be at-	Paragraph 1 is amended.
tached when applying for	tached when applying for	Any change in the speci-
change of the specifica-	change of the specifica-	fications of a medical
tions on a medical device	tions on a medical device	device (such as new
permit license:	permit license:	availability of contact
1.Application form for	1.Application form for	lenses in different diame-
change in medical de-	change in medical de-	ters or colors) shall be
vice permit license.	vice permit license.	done after evaluated by
2.Original copy of the	2.Original copy of the	the original designer or
medical device permit	medical device permit	manufacturer of the
license.	license.	product, so as to ensure
3.Original copy of the	3.Original copy of the	the safety and efficacy of
already approved in-	already approved in-	the product. Therefore,
struction leaflet	struction leaflet	the amendment requires
stamped with tally im-	stamped with tally im-	that the comparison and
		·
pression of the central	pression of the central	explanation of the

Amended Provisions		
health	competent	au-
thority.		

- 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: 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.
- 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. The original copy of the

Existing Provisions

- 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: 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.
- 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

Explanations

- 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. 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

comparison and explanation of the changed specifications and the originally approved specifications issued by the original manufac-

8.The original copy of the manufacture and free sale certificate of the country of origin.

turer;

- 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 domesticallymanufactured 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

Existing Provisions

- 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

Explanations

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	Evicting Provisions	Evaluations
	Existing Provisions	Explanations
central health competent	the one required testing by the central health	
authority, two (2) copies	,	
of the documents speci-	competent authority shall	
fied in Subparagraph 5 of	also submit for testing.	
Paragraph 1 shall be	The medical device	
submitted, and submis-	applying for registration	
sion for testing is re-	in Paragraph 1 shall be in	
quired.	conformity with related	
The medical device	rules or regulations an-	
applying for registration	nounced by the central	
in Paragraph 1 shall be in	health competent author-	
conformity with related	ity, and the documents	
rules or regulations an-	exempted from submis-	
nounced by the central	sion shall be kept in the	
health competent author-	manufacturing factory.	
ity, and the documents	The central health com-	
exempted from submis-	petent authority may	
sion shall be kept in the	order its submission	
manufacturing factory.	when necessary.	
The central health com-		
petent authority may		
order its submission		
when necessary.		
Article 26 The following	Article 26 The following	Subparagraph 11 of Para-
documents shall be at-	documents shall be at-	graph 1 is added. Any
tached when applying for	tached when applying for	change in the efficacy of a
change in medical device	change in medical device	medical device (for exam-
efficacy, indication, per-	efficacy, indication, per-	ple, the graft materials
formance, instruction for	formance, instruction for	previously for dental
use, or dosage on a medi-	use, or dosage on a medi-	purposes only may also be
cal device permit, the	cal device permit, the	used for other bone defects)
following documents shall	following documents shall	shall be done after evaluat-
be submitted:	be submitted:	ed by the original designer
1.Application form for	1.Application form for	or manufacturer of the
change in medical de-	change in medical de-	product, so as to ensure the
vice permit license.	vice permit license.	safety and efficacy of the
•	·	
2.Original copy of the	2.Original copy of the	product. Therefore, the

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

Amended Provisions	Existing Provisions	Explanations
instrument product, an	instrument product, an	
operation manual or a	operation manual or a	
service manual covers	service manual covers	
all of the abovemen-	all of the abovemen-	
tioned items may be a	tioned items may be a	
substitution.	substitution.	
7.The original copy of the	7.The original copy of the	
manufacture and free	manufacture and free	
sale certificate of the	sale certificate of the	
country of origin.	country of origin.	
8.The original copy of	8.The original copy of	
foreign original manu-	foreign original manu-	
facturer authorization	facturer authorization	
letter.	letter.	
9.Theoretical basis and	9.Theoretical basis and	
relevant research re-	relevant research re-	
ports and data.	ports and data.	
10.Clinical trial reports.	10.Clinical trial reports.	
11. The original copy of	In the event of applying	
the comparison and ex-	for change of a domesti-	
planation of the	cally manufactured medi-	
changed particulars and	cal device, Subparagraph 7	
the originally approved	and 8 and of the preced-	
particulars issued by the	ing paragraph shall be	
original manufacturer.	exempted.	
In the event of	In the event of al-	
applying for change of a	ready a product in the	
domestically manufac-	market similar to the	
tured medical device,	medical device applying	
Subparagraph 7 and 8	for changes of Paragraph	
and of the preceding	1, the documents speci-	
paragraph shall be ex-	fied in Subparagraphs 9	
empted.	and 10 of Paragraph 1	
In the event of al-	may be waived.	
ready a product in the	The medical device	
market similar to the	applying for registration	
medical device applying	in Paragraph 1 and Para-	

Amended Provisions	Existing Provisions	Explanations
for changes of Paragraph	graph 3 shall be in con-	Ελριαπατίοπο
1, the documents speci-	formity with related rules	
	•	
fied in Subparagraphs 9	or regulations announced	
and 10 of Paragraph 1	by the central health	
may be waived.	competent authority, and	
The medical device	the documents exempted	
applying for registration	from submission shall be	
in Paragraph 1 and Para-	kept in the manufacturing	
graph 3 shall be in con-	factory. The central	
formity with related rules	health competent author-	
or regulations announced	ity may order its submis-	
by the central health	sion when necessary.	
competent authority, and		
the documents exempted		
from submission shall be		
kept in the manufacturing		
factory. The central		
health competent author-		
ity may order its submis-		
sion when necessary.		
Article 28 The following	Article 28 The following	1. Paragraph 5 is amended.
documents shall be at-	documents shall be at-	For the change of the
tached when applying for	tached when applying for	address of the manufac-
change in address of	change in address of	turing factory of Class III
manufacturing factory	manufacturing factory	IVDs, documents regard-
(including the country of	(including the country of	ing pre-clinical testing
origin):	origin):	and quality control con-
1.Application form for	1.Application form for	ducted by the original
change in medical de-	change in medical de-	manufacturer are re-
vice permit license.	vice permit license.	quired in accordance
2.Original copy of the	2.Original copy of the	with Article 12, to verify
medical device permit	medical device permit	the safety and functional-
license.	license.	ity of the products.
3.Original manufacturer	3.Original manufacturer	Therefore, new contents
covering letter that ex-	covering letter that ex-	are added to the original
plains the change in	plains the change in	provisions to avoid any
manufacturing factory	manufacturing factory	doubts during reviews
manufacturing factory	mandiacturing factory	doubts during reviews

Amended Provisions 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

Existing Provisions 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

Explanations

- 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	house-numbering system	
change, document for	change, document for	
Subparagraph 5 of Para-	Subparagraph 5 of Para-	
graph 1 may be exempt-	graph 1 may be exempt-	
ed, a certificate issued by	ed, a certificate issued by	
government shall be	government shall be	
submitted; in the case of	submitted; in the case of	
imported medical devic-	imported medical devic-	
es, the certificate shall be	es, the certificate shall be	
notarized by R.O.C (Tai-	notarized by R.O.C (Tai-	
wan) foreign affairs office.	wan) foreign affairs office.	
In the case of a Class	When the medical	
III IVD, the application for	device for which an appli-	
change shall be in con-	cation to change manu-	
formity with the preced-	facturing factory address	
ing four paragraphs.	has been made is a Class	
Moreover, two (2) copies	III IVD, in addition to the	
of the documents stating	preceding 4 paragraphs,	
the test specifications and	two copy of each of the	
methods for pre-clinical	following items, including	
testing <u>and quality con-</u>	pre-clinical testing and	
trol conducted by the	the test specifications and	
<u>original manufacturer</u> ,	methods, the original test	
the original test records,	records, and the test	
and the test result reports	reports of the quality	
shall be submitted. If the	control conducted by the	
IVD is required to under-	original manufacturer,	
go testing, as announced	shall be submitted. When	
by the central health	the type of device is an-	
competent authority,	nounced as the one re-	
submission for testing is	quired testing by the	
also required.	central health competent	
For medical devices	authority, the applicant	
for which an application	shall also submit for test-	
for change of the address	ing.	
of the manufacturing		
<u>factory</u> is submitted in		

Amended Provisions	Existing Provisions	Explanations
accordance with Para-		
graph 1, the central		
health competent author-		
ity may, if necessary,		
order submission of tech-		
nical documentation such		
as relevant documents		
concerning product struc-		
ture, materials, specifica-		
tions, performance, in-		
tended use, and draw-		
ings, pre-clinical testing		
documents, and test		
results of quality control		
by the original manufac-		
turer.		
Article 35 The following	Article 35 The following	1. Paragraph 4 is added. To
documents shall be at-	documents shall be at-	strengthen the manage-
tached when applying for	tached when applying for	ment of Class I medical
extension of the validity	extension of the validity	devices, the uploading of
period of a medical de-	period of a medical de-	the instructions, labels,
vice permit license:	vice permit license:	and outer boxes of Class I
1.A medical device permit	1.A medical device permit	medical devices has be-
license validity period	license validity period	come a requirement for
extension application	extension application	applying for extension.
form approved by the	form approved by the	2. The text in Subparagraph
special municipality,	special municipality,	2 of Paragraph 6 is
county and city health	county and city health	amended.
competent authority of	competent authority of	3. Paragraph 7 is added. If
the pharmaceutical	the pharmaceutical	there are doubts about
company's locality.	company's locality.	the safety and efficacy of
2.Original copy of the	2.Original copy of the	the product concerned
medical device permit	medical device permit	by the application for
license.	license.	extension, the central
3.The original copy of the	3.The original copy of the	health competent au-
manufacture and free	manufacture and free	thority may order the
sale certificate of the	sale certificate of the	manufacturer to submit

Amended Provisions	Existing Provisions	Explanations
country of origin.	country of origin.	relevant documents, so
4.Original copy of foreign	4.Original copy of foreign	as to ensure the efficacy
original manufacturer	original manufacturer	and safety of the prod-
continual authorization	continual authorization	uct.
letter.	letter.	
5.Certificate of in con-	5.Certificate of in con-	
formity with the GMP	formity with the GMP	
for Medical Devices.	for Medical Devices.	
Product items in ac-	Product items in ac-	
cordance with the Arti-	cordance with the Arti-	
cle 4 Appendix II of the	cle 4 Appendix II of the	
Regulations for Govern-	Regulations for Govern-	
ing the Management of	ing the Management of	
Medical Device are ex-	Medical Device are ex-	
empted from this sub-	empted from this sub-	
paragraph.	paragraph.	
The medical device	The medical device	
applying for foregoing	applying for foregoing	
paragraph application is	paragraph application is	
commissioned to manu-	commissioned to manu-	
facture or analysis, it shall	facture or analysis, it shall	
be in conformity with the	be in conformity with the	
Regulations for Medica-	Regulations for Medica-	
ment Contract Manufac-	ment Contract Manufac-	
ture and Analysis.	ture and Analysis.	
In the event of ap-	In the event of ap-	
plying for extension of	plying for extension of	
the validity period of a	the validity period of a	
medical device permit	medical device permit	
license for a domestically	license for a domestically	
manufactured medical	manufactured medical	
device, the applicant is	device, the applicant is	
exempted from submit-	exempted from submit-	
ting documents specified	ting documents specified	
in Subparagraph 3 and 4	in Subparagraph 3 and 4	
of Paragraph 1.	of Paragraph 1.	
In the event of ap-	In the event of ap-	

Amended Provisions	Existing Provisions	Evolunations
plying for extension of a	Existing Provisions plying extension of the	Explanations
Class I medical device	validity period of a medi-	
	cal device permit license	
permit license, this article	of a Class I medical de-	
shall apply, and the in-		
structions, labels, and	vice, in addition to com-	
outer box shall first be	plying this article, Articles	
uploaded to the infor-	14 and 16 shall be applied	
mation system specified	mutatis mutandis.	
by the central health	If meeting one of the	
competent authority.	following circumstances,	
In the event of ap-	documents of the Sub-	
plying extension of the	paragraphs 5 in the Para-	
validity period of a medi-	graph 1 may be substitut-	
cal device permit license	ed with photocopies of	
of a Class I medical de-	documents verifying	
vice, in addition to com-	compliance with GMP for	
plying this article, Articles	Pharmaceuticals:	
14 and 16 shall be applied	1.The medical device	
mutatis mutandis.	applying for registration	
If meeting one of the	was regulated as a	
following circumstances,	pharmaceutical product	
documents of the Sub-	before. This rule applies	
paragraphs 5 in the Para-	within three years from	
graph 1 may be substitut-	the date of proclama-	
ed with photocopies of	tions of listing change.	
documents verifying	2.The medical device was	
compliance with GMP for	regulated as a pharma-	
Pharmaceuticals:	ceutical product before	
1.The medical device	January 1, 2013. This	
applying for registration	rule applies within three	
was regulated as a	years from the promul-	
pharmaceutical product	gation date of the Sep-	
before. This rule applies	tember 5, 2014	
within three years from	amendment to this	
the date of proclama-	Regulation. The manu-	
tions of listing change.	facturing factory with	
2.The medical device was	valid medical device li-	

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

Amended Provisions

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;

Existing Provisions

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; **Explanations**

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	Characters in any other	
language shall be smaller	language shall be smaller	
than Chinese ones.	than Chinese ones.	
Holders of permit li-		
censes for approved and		
launched Class I medical		
devices shall, within one		
(1) month after obtaining		
the permit licenses, up-		
load the instructions,		
labels, and outer boxes to		
the information system		
specified by the central		
health competent author-		
ity. Permit license holders		
shall assume the obliga-		
tions to ensure the au-		
thenticity of all uploaded		
contents, including the		
names of the uploaded		
documents, labels, in-		
structions, packaging,		
trademarks, and draw-		
ings.		
Permit license hold-		
<u>ers who obtain Class I</u>		
medical device permit		
<u>licenses</u> before the		
amendment to this Regu-		
lation comes into force		
shall, within six (6)		
months from the date of		
promulgation of the 000		
Amendment to this Regu-		
lation, upload the instruc-		
tions, labels, and outer		
boxes in accordance with		

Amended Provisions	Existing Provisions	Explanations
the preceding paragraph.		
Article 37 The product	Article 37 The product	Subparagraph 5 of Para-
name of a medical device	name of a medical device	graph 1 is added. Since the
shall comply with the	shall comply with the	review process for medical
following regulations:	following regulations:	devices exclusively for
1.A product name shall	1.A product name shall	export is different from that
not use pharmaceutical	not use pharmaceutical	for domestically manufac-
name, trademark, or	name, trademark, or	tured medical devices, it is
name of manufacturer	name of manufacturer	explicitly stipulated that the
from others, unless	from others, unless	Chinese and English names
trademark awarded or	trademark awarded or	of medical devices exclu-
authorization obtained.	authorization obtained.	sively for export shall not be
2.A product name shall	2.A product name shall	the same as those of
not be the same as oth-	not be the same as oth-	domestically manufactured
er medical device, or	er medical device, or	medical devices. Thus, any
involved in counterfeit-	involved in counterfeit-	confusion between medical
ing or insinuation.	ing or insinuation.	devices exclusively for
3.Product name shall not	3.Product name shall not	export and domestically
involve in misrepresen-	involve in misrepresen-	manufactured medical
tation, overstatement,	tation, overstatement,	devices can be avoided.
or leading people in im-	or leading people in im-	
proper association with	proper association with	
medical device and/or	medical device and/or	
efficacy.	efficacy.	
4.Chinese product name	4.Chinese product name	
shall not contain any	shall not contain any	
character in any other	character in any other	
language or in numbers,	language or in numbers,	
unless phrases used	unless phrases used	
contain meaning direct-	contain meaning direct-	
ly related, or English	ly related, or English	
trademarks contains	trademarks contains	
special meaning and	special meaning and	
approved by the central	approved by the central	
health competent authority.	health competent au- thority.	
·	•	
5.The Chinese and English	5.A product name shall	

	E	·
Amended Provisions	Existing Provisions	Explanations
names of medical de-	not be in other improp-	
vices exclusively for ex-	er situations as a name	
port shall not be the	of medical device.	
same as those of do-	The precedence of	
mestically manufac-	medical device names	
tured medical devices.	that are identical or simi-	
6.A product name shall	lar shall be determined	
not be in other improp-	on the basis of the prece-	
er situations as a name	dence of trademarks,	
of medical device.	company names, or other	
The precedence of	identifiable names.	
medical device names	The central health	
that are identical or simi-	competent authority may	
lar shall be determined	review the name of a	
on the basis of the prece-	medical device already	
dence of trademarks,	approved for sale in ac-	
company names, or other	cordance with regulations	
identifiable names.	of the foregoing two par-	
The central health	agraphs.	
competent authority may		
review the name of a		
medical device already		
approved for sale in ac-		
cordance with regulations		
of the foregoing two par-		
agraphs.		