

Medical technology companies in China (both AdvaMed members and non-members) may participate in this certification program. This certification is for non-members. The certification affirms that the company has agreed to abide by the AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("AdvaMed China Code") and to adopt policies and procedures to implement the AdvaMed China Code as part of an effective compliance program. The Certification and the Logo License Program operate on a Calendar Year basis and both are now being accepted for 2021.

A New Certification requires (Attachment A):

Two Signatures

- Signature of the most senior executive responsible for operations in China
- Signature of the Chief Compliance Officer for China or other senior individual with equivalent responsibilities (CCO)

Compliance Contact Information

<input type="checkbox"/> Compliance Contact (Individual or Dept. Name) + Telephone# and/or Email Address (Compliance Hotline Optional)	- OR -	<input type="checkbox"/> Compliance Hotline
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Electronic Submission

- Please transmit a PDF electronic copy via email to:
ChinaCode@AdvaMed.org
- Please email a graphic file of your Company's logo to:
ChinaCode@AdvaMed.org

A Renewal Certification requires (Attachment B):

One Signature

- The signature of the Chief Compliance Officer or other senior individual with equivalent responsibilities (CCO), to attest that their company has previously certified and that the company continues to abide by the AdvaMed China Code.

Updated Compliance Contact Information

- Update Compliance Contact Information if it has changed from the previous certification

Electronic Submission

- Please transmit a PDF electronic copy via email to:
ChinaCode@AdvaMed.org

AdvaMed Code Logo License Agreement (Attachment C):

AdvaMed has developed a distinctive AdvaMed China Code Supporter Logo ("Logo") for medical technology manufacturers that have executed the Certification of Adoption of the AdvaMed China Code ("Certification") and wish to use the Logo.

China Code Logo



A New Participant in the Logo Program requires:

- A Completed Certification or Renewal Certification form (meeting the requirements noted above)
- A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to ChinaCode@AdvaMed.org
- Contact information to receive the invoice for the Royalty Payment (\$300/ year)

For Question regarding the Certification, Renewal Certification, or the Logo Supporter Program, contact:

Emily Dahl
edahl@advamed.org

A Renewal Participant in the Logo Program requires:

- A Completed Certification or Renewal Certification form (meeting the requirements noted above)
- A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to CodeCertification@AdvaMed.org
- Updated Contact information to receive the invoice the invoice for the Royalty Payment (\$300/ year)

Attachment A

New Non-Member Certification Form
&
Certification FAQs



**2021 NON-MEMBER CERTIFICATION OF ADOPTION OF THE
ADVAMED CHINA CODE OF ETHICS**

Pursuant to the AdvaMed Code of Ethics on Interactions with Health Care Professionals in China (“AdvaMed China Code”), medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the AdvaMed China Code and have implemented policies and procedures to implement the AdvaMed China Code as part of an effective compliance program. This certification for non-members requires (i) the most senior executive responsible for operations in China and (ii) the Chief Compliance Officer for China or other senior individual with equivalent responsibilities to sign and affirm that their company has taken the steps identified below.

On behalf of _____
(identify Company name or relevant portions/subsidiaries) (“Company”), I certify that, to the best of my knowledge and as of the date of this certification:

I have read and am familiar with the provisions of the AdvaMed China Code, including the Frequently Asked Questions.

I am knowledgeable about our Company’s compliance and ethics program (“Compliance Program”) as it relates to the AdvaMed China Code.

Our Company requires all applicable officers, employees, and agents to abide by the AdvaMed China Code for all interactions involving Health Care Professionals as that term is defined in the AdvaMed China Code.

Our Company has made a copy of the AdvaMed China Code and/or a link to the AdvaMed China Code available on our Company’s public website.

Our Company adopted the AdvaMed China Code and implemented an appropriately tailored effective compliance program related to our interactions with Health Care Professionals by taking the following steps:

1. **Written Policies and Procedures:** Established and implemented policies and procedures consistent with the provisions of the AdvaMed China Code.
2. **Compliance Officer/Committee:** Established effective oversight over the Compliance Program applicable to China, including: (a) identifying a senior manager in our Company who is responsible for compliance with our Company’s policies and procedures consistent with the AdvaMed China Code; and (b) creating a compliance committee or other equivalent process comprised of senior leadership who are actively engaged in the oversight of our Compliance Program applicable to China.



3. Training and Education: Provided training to those employees and contractors whose job requirements make the information relevant on Company policies that are based on the AdvaMed China Code, and implemented procedures to ensure ongoing training programs for such new employees and contractors.
4. Lines of Communication: Established a resource for employees to ask questions as well as a reporting mechanism to facilitate anonymous internal reporting of suspected violations of Company policies that are based on the AdvaMed China Code.
5. Auditing and Monitoring: Instituted processes within our Company to conduct internal monitoring and auditing of the Company policies and procedures that are based on the AdvaMed China Code and to assess the overall effectiveness of our Company's Compliance Program.
6. Enforcement: Established a disciplinary process for violations of those policies and procedures that support the AdvaMed China Code.
7. Corrective Action: Established a process to respond to suspected deficiencies or violations of Company policies that are based on the AdvaMed China Code.

CEO Signature
(or equivalent) _____

CCO Signature
(or equivalent) _____

Name: _____

Name: _____

Date: _____

Date: _____

Title: _____

Title: _____

Company/
Division: _____

Company/
Division: _____

Mailing
Address: _____

Mailing
Address: _____

COMPLIANCE CONTACT INFORMATION (REQUIRED):

Name: _____
Phone: _____
and/or
Email: _____

- OR -

Hotline Number: _____

NON-MEMBER CERTIFICATION FAQS

Q: What does the Certification require?

A: The Certification requires companies to self-certify that they have adopted policies at least as stringent as or policies consistent with the AdvaMed China Code and implemented seven elements of an effective compliance program. These elements outline specific programs and processes firms must maintain to ensure effective compliance with the Code.

Q: Are AdvaMed Members required to certify adoption?

A: No. The certification is strictly voluntary. However, AdvaMed strongly encourages all medical technology manufacturers to adopt effective compliance programs consistent with the AdvaMed China Code. Further, AdvaMed requires that companies wishing to participate on the AdvaMed China Board of Directors must submit a Certification as to compliance with the AdvaMed China Code.

Q: Who must execute the Certification?

A: The most senior executive responsible for operations in China of the legal entity seeking the Certification must sign and date the Certification. For companies headquartered in China, this would be the Chief Executive Officer (CEO) or individual with equivalent responsibility. For companies headquartered outside of China, this would be the most senior representative of the China operation. In addition, the Chief Compliance Officer (CCO) for China or other senior individual with equivalent responsibilities for the legal entity seeking the license must sign and date the Certification. These individuals may wish to consult with legal counsel regarding the implications of certification prior to signing the Certification.

Q: How often must my company complete the Certification?

A: The Certification must be renewed annually.

Q: If my company acquires a new business unit that has not adopted the AdvaMed China Code, is my certification still valid?

A: Certifying companies should make every effort to adopt the AdvaMed China Code and implement an effective compliance program with regard to a newly acquired business unit as quickly as possible. The certification is made as of the date it is signed and applicable to the company as it existed at that time; a later acquisition would not violate its terms. However, a company should not renew its annual certification the following year if it has not adopted the AdvaMed China Code across all of its business units for which the AdvaMed China Code is relevant.

The only circumstance in which a company may certify adoption of the AdvaMed China Code by a smaller subset of its business units is when an acquisition may have closed too recently before the date of annual certification for the acquiring company to have completed its compliance evaluation and made any necessary adjustments to bring the newly acquired business unit into compliance with the Code. In such cases, the acquiring company may renew its certification for its other businesses but must include a notification that the certification does not apply to the newly-acquired business unit. Unless the company provides a date at which the new unit will be in compliance and covered by the certification, the company will be expected to include the new unit in the following year's certification.

Q: Is there a standard set of attributes that constitute an effective compliance program?

A: A company's compliance program should be appropriately tailored, meaning it will take into account the company's size, resources, lines of business, and workforce. Many companies' compliance policies and procedures will be tailored to address the specific types of risks that apply to their operations. This could result in some companies' policies and procedures differing from others' while still adhering to an effective compliance program.

Q: How does my company's certification of adoption of the AdvaMed China Code relate to the Code of Ethics Supporter Logo?

A: If your company certifies adoption of the China Code, you have the additional option of licensing the China Code of Ethics Supporter Logo—a symbol of that certification and commitment to compliance. The logo may be used on business cards, trade show booths, brochures and in certain other means to visible demonstrate the company's commitment to the AdvaMed China Code. Companies are strongly encouraged to take this additional step.

Q: What if my company manufactures pharmaceuticals or biologics in addition to medical technologies covered by the AdvaMed China Code?

A: A company may obtain a certification for its medical technology component, division or affiliate, rather than for the company as a whole, and the certification would apply to the business units and employees whose activities make the AdvaMed China Code relevant. Any Logo materials used by the company should make this distinction clear.

Attachment B

Non-Member Renewal Certification



**2021 NON-MEMBER RE-CERTIFICATION OF ADOPTION OF
THE ADVAMED CHINA CODE OF ETHICS**

Pursuant to the AdvaMed Code of Ethics on Interactions with Health Care Professionals in China (“AdvaMed China Code”), medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the AdvaMed China Code and have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program. This non-member renewal certification requires a company’s Chief Compliance Officer (CCO) or other senior individual with equivalent responsibilities to sign and affirm that their company has previously certified and that the company continues to abide by the AdvaMed China Code.

On behalf of _____
(identify Company name or relevant portions/subsidiaries) (“Company”), I certify that, to the best of my knowledge and as of the date of this certification:

Our Company has previously certified that we will abide by the AdvaMed China Code, and that we have implemented policies and procedures to implement the AdvaMed China Code as part of an effective compliance program.

I further certify that, since the time of our Company’s most recent certification, there have been no material changes to the status of our Company in this regard.

CCO Signature
(or equivalent) _____

Name: _____

Date: _____

Title: _____

Company/
Division: _____

Mailing
Address: _____

UPDATE FOR COMPLIANCE CONTACT INFORMATION (Required):

Name: _____

Phone: _____

and/or

Email: _____

- OR -

Hotline Number:

Attachment C

China Code of Ethics Supporter Logo License
Supplement & Logo FAQs



2021 NON-MEMBER ADVAMED CHINA CODE LOGO LICENSE SUPPLEMENT

AdvaMed developed a distinctive China Code of Ethics Supporter Logo (“Logo”) for medical technology manufacturers that have executed the Certification of Adoption of the AdvaMed China Code of Ethics (“AdvaMed Certification”) and wish to use the Logo. The Logo is intended to provide a visible symbol of a certifying medical technology company’s commitment to the ethical standards embodied by the AdvaMed China Code and to promote awareness about the AdvaMed China Code among industry, health care professionals, and the general public.

Companies seeking to use the Logo must sign the following nonexclusive license provision. AdvaMed retains the right to revoke this License for a Company’s failure to abide by the terms of this Logo License Supplement.

On behalf of _____
(identify company name or name of relevant portions/subsidiaries), I agree to abide by the following terms to receive a revocable, non-transferable, nonassignable, non-exclusive license to use an unaltered version of the Logo on marketing materials, business cards, and displays at meetings and conferences, and stationery:

- 1) The Logo may not be used on any product;
- 2) The licensee acknowledges and agrees that the right to use the Logo, as well as the actual use of the Logo, is not an endorsement by AdvaMed;
- 3) The right to use the Logo is subject to the licensee’s annual completion of the AdvaMed Certification and payment of a royalty (U.S. \$300 / year), which royalty may be adjusted by AdvaMed from time to time; and
- 4) The royalty payment is made solely in exchange for the use of the Logo, and such payment does not entitle the licensee to any other benefit or service from AdvaMed.

Signature _____ Date: _____
Chief Compliance Officer (or Equivalent)

Name: _____

Title: _____

Please email the invoice for the royalty payment to:

Name: _____

Use PO or Reference#:

Email: _____

Please email the confirmation of payment receipt and the logo file to:

Name: _____

Email: _____

AdvaMed China Code of Ethics Supporter Logo LOGO FAQs



Q: What is the purpose of AdvaMed's China Code of Ethics Supporter Logo?

A: AdvaMed's China Board of Directors has embraced an ongoing commitment to promote ethical interactions among medical technology manufacturers and health care providers. The Logo is a visible symbol of medical technology manufacturers' commitment to the AdvaMed China Code of Ethics and will let health care professionals know at a glance that they are dealing with a company that strives to meet the ethical standards reflected in the AdvaMed China Code and has an effective compliance program in place.

Q: How may I use the AdvaMed China Code of Ethics Supporter Logo?

A: Licensees may use the AdvaMed China Code of Ethics Supporter Logo on print or electronic materials to represent their commitment to an effective compliance program and ethical interactions with health care providers. For example, licensees may print the logo on annual reports, promotional material, business cards, stationery and conference banners and signs. The logo may not be used in a manner or associated with text that implies that AdvaMed has endorsed or approved a licensee's products, technology or individual compliance plan or practices.

Q: How do I obtain the right to use the AdvaMed China Code of Ethics Supporter Logo?

A: A non-member medical technology manufacturer may obtain a one (1) year right to use the AdvaMed China Code of Ethics Supporter Logo upon submission of a Certification/Renewal Certification, a properly executed License Agreement and submission of the Royalty Fee (U.S. \$300 / year).

Q: Who must execute the License Agreement?

A: The Chief Compliance Officer (CCO) (or equivalent) of the legal entity seeking the license must sign and date the License Agreement. The CCO may wish to consult with legal counsel regarding the implications of licensure prior to signing the License Agreement.