



**中国食品药品检定研究院与
美国国家标准协会
合作备忘录**

中国食品药品检定研究院（国家食品药品监督管理总局医疗器械标准管理中心）和美国国家标准协会（ANSI）作为合作伙伴，双方共同认为，标准的一致性有利于医疗器械监管和促进国际贸易。双方希望在以下标准化工作方面开展技术合作：

合作目标

双方共同认为应加强参与国际或地区的标准组织机构（标准组织机构范围不仅限于国际标准化组织机构，例如 ISO、IEC）的活动，并在标准管理和相关工作项目上进行交流研讨，对提供更符合监管需要和产业发展需求的标准开展定期交流和长期合作具有重要作用和意义。

在完善标准体系管理方面，通过双方的合作，共同推进国际标准化工作的发展。

合作范围

中国食品药品检定研究院（NIFDC）和美国国家标准协会（ANSI）双方本着互惠互利的原则，希望在以下方面开展合作：

- (1).鼓励双方以及由双方协调的医疗器械标准化组织参与合作活动，共同参与国际标准的制修订工作，信息共享；
- (2).加强双方在医疗器械热点技术领域标准化工作的专家技术交流研讨（详见附件 1）；
- (3).鼓励双方开展多种形式的合作与交流活动；
- (4).鼓励双方以多种形式培养医疗器械标准化技术人才；
- (5).鼓励双方采用多种形式共享医疗器械标准相关信息。

其他事项

- (1).双方合作中产生的任何问题，本着平等互利的原则，由合作双方协商解决；
- (2)本合作备忘录是经双方协商一致后，达成的书面协议，未经双方同意不得变更本合作备忘录中的条款内容；
- (3)本合作备忘录在终止前有效。任何一方如终止本合作应至少提前 6 个月以书面形式通知另一方。

签字

中国食品药品检定研究院

美国国家标准协会

职位： 副院长

职位：

签字：

签字：

日期： 2014.10.16

日期： 2014.10.16

附件 1:

在合作备忘录中，中国食品药品检定研究院（NIFDC）和美国国家标准协会（ANSI）同意在多项医疗器械标准化活动中开展合作。双方在医疗器械热点领域的技术交流和研讨内容包括：

- 1.医疗器械标准体系信息交流合作：
 - (1).开展医疗器械标准体系规划和相关政策的技术研讨；
 - (2).开展标准管理方法和程序的技术研讨；
 - (3).开展医疗器械热点领域，例如风险管理、医用软件、医用机器人技术、数字医疗、新型生物材料和体外诊断产品等领域的标准化技术研讨。
- 2.医疗器械的分类、命名和编码
 - (1).开展医疗器械的分类、命名和编码的技术研讨；
 - (2).开展医疗器械唯一标识(UDI)的技术研讨；
 - (3).开展全球医疗器械术语系统(GMDN)的技术研讨。
- 3.其他双方当事人同意的项目。



**Memorandum of Cooperation
Between
American National Standards Institute
And
National Institutes for Food and Drug Control**

As cooperation partners, American National Standards Institute (ANSI) and National Institutes for Food and Drug Control (Center for Medical Device Standardization Administration, CFDA) have agreed that consistency in standards is good for the supervision of medical devices and the promotion of international trade, and the two sides shall cooperate in the following standardization work:

Cooperation Objective

The two sides agree that they should increase their participation in the activities of international or regional standardization organizations (standardization organizations are not limited to the organizations such as ISO and IEC), and that they should carry out exchange and discussion with regard to standardization administration and other related work, which will prove to be of significant importance to the periodical exchange and long-term cooperation on providing standards that will better meet regulatory and industrial development needs.

The two sides will carry out complementary cooperation on improving the standard system administration so as to jointly promote the development of the international standardization work.

Cooperation Scope

Pursuant to the principle of mutual benefit, American National Standards Institute (ANSI) and National Institutes for Food and Drug Control (NIFDC) shall cooperate on specific initiatives including:

- (1). Encourage the two sides and medical device standardization organizations coordinated by the two sides to take part in cooperation work, and jointly take part in the formulation of international standards and the sharing of information.
- (2). Enhance the two sides' expert technology exchange and discussion with regard to the standardization work in hot technical areas in the medical device industry. (See Appendix I for more details)
- (3). Encourage the hosting of a variety of cooperation and exchange activities.
- (4). Encourage the two sides to foster a variety of ways to educate personnel on medical device standards.
- (5). Encourage the two sides to share information related to medical device standards via multiple means.

Other Provisions

- (1). Any and all problems arising from the cooperation between the two sides shall be resolved through mutual negotiation pursuant to the principle of equality and mutual benefit.
- (2) This Memorandum of Cooperation is a written agreement reached between the two sides through mutual negotiation. Its contents shall not be revised without mutual consent.
- (3) This Memorandum of Cooperation shall remain effective until it is terminated. Any side intending to terminate this cooperation shall send the other side a written notice at least 6 months in advance.

Signatures

**National Institutes
for Food and Drug Control**

**American National
Standards Institute**

Title: Deputy Director-general
Policy

Title: Vice President, International

Signature: 

Signature: 

Date: 2014.10.16.

Date: 2014.10.16

Appendix I

Under this Memorandum of Cooperation, NIFDC and ANSI agree to cooperate in a series of medical device standardization activities. The two sides' expert technology exchange and discussion with regard to the hot technical areas in the medical device industry, whose contents include:

1. Medical device standard system information exchange and cooperation:
 - a. Carry out technical discussion with regard to medical device standard system plan and related policies;
 - b. Carry out technical discussion with regard to methodology and procedure of standardization administration;
 - c. Carry out standardization technical discussion with regard to hot areas in the medical device industry, such as risk management, medical software, medical robot technology, digital medical technology, new bio-material and in vitro diagnosis, etc.
2. The classification, naming and coding of medical devices
 - a. Technical discussion with regard to the classification, naming and coding of medical devices;
 - b. Technical discussion with regard to Unique Device Identification (UDI);
 - c. Technical discussion with regard to Global Medical Device Nomenclature (GMDN).
3. Other items agreed between the two sides.