



Shanghai CILS® Law Firm
上海信石®律师事务所

Room 2615, Enterprise Square
No. 228 Meiyuan Road, Shanghai 200070
People's Republic of China

中国上海市梅园路 228 号
企业广场 2615 室, 邮编: 200070

Tel: +86 21 80127725
Fax: +86 21 80127724
www.cilslaw.com

法律法规简报 2021-09-29

Legal Update 2021-09-29

目录

Contents

◇ [市场监管总局公布《医疗器械注册与备案管理办法》](#)

SAMR Issues Administrative Measures for the Registration and Record-filing of Medical Devices

◇ [最高法：调整中级人民法院管辖第一审民事案件标准](#)

SPC Adjusts Criteria for the Jurisdiction of Intermediate People's Courts over Civil Cases of First Instance

◇ [市场监管总局就修改《电子商务法》征求意见](#)

SAMR Proposes to Amend the E-Commerce Law

◇ [最高法启动四级法院审级职能定位改革试点](#)

SPC Launches Pilot Reform on Defining Trial Level Functions under the Four-tiered Court System

一、市场监管总局公布《医疗器械注册与备案管理办法》 2021.08.31

SAMR Issues Administrative Measures for the Registration and Record-filing of Medical Devices



Shanghai CILS® Law Firm
上海信石®律师事务所

Room 2615, Enterprise Square
No. 228 Meiyuan Road, Shanghai 200070
People's Republic of China

中国上海市梅园路 228 号
企业广场 2615 室, 邮编: 200070

Tel: +86 21 80127725
Fax: +86 21 80127724
www.cilslaw.com

近日，国家市场监督管理总局发布《医疗器械注册与备案管理办法》（下称《办法》），自 10 月 1 日起施行。

Recently, the State Administration for Market Regulation ("SAMR") has issued the *Administrative Measures for the Registration and Record-filing of Medical Devices* (the "*Measures*"), which will become effective on October 1, 2021.

《办法》规定，第一类医疗器械实行产品备案管理。第二类、第三类医疗器械实行产品注册管理。进口第一类医疗器械备案，备案人向国家药品监督管理局提交备案资料。进口第二类、第三类医疗器械由国家药品监督管理局审查，批准后发给医疗器械注册证。

The *Measures* stipulate that Class I medical devices shall be subject to product record-filing management. Class II and Class III medical devices shall be subject to product registration management. To file the imported Class I medical devices for the record, the filing persons shall submit the filing materials to the National Medical Products Administration ("NMPA"). Imported Class II and Class III medical devices shall be reviewed by the NMPA, and a medical device registration certificate will be issued after approval.

同时，《办法》明确，申请人、备案人应当为能够承担相应法律责任的企业或者研制机构。申请人、备案人应当建立与产品相适应的质量管理体系，并保持有效运行。《办法》还指出，国家药监局建立并分步实施医疗器械唯一标识制度，申请人、备案人应当按照相关规定提交唯一标识相关信息，保证数据真实、准确、可溯源。

Also, the *Measures* clarify that, applicants or filing persons, which should be enterprises or research institutes that can bear corresponding legal liability, shall establish a quality management system that fits in their products and maintain its effective operation. The *Measures* also point out that the NMPA will establish and implement a unique identification system for medical devices step by step. Applicants and filing persons should submit information pertaining to unique identification pursuant to relevant regulations and ensure that the data is truthful, accurate and traceable.



Shanghai CILS® Law Firm
上海信石®律师事务所

Room 2615, Enterprise Square
No. 228 Meiyuan Road, Shanghai 200070
People's Republic of China

中国上海市梅园路 228 号
企业广场 2615 室, 邮编: 200070

Tel: +86 21 80127725
Fax: +86 21 80127724
www.cilslaw.com

(Source: http://gkml.samr.gov.cn/nsjg/fgs/202108/t20210831_334228.html)

二、最高法：调整中级人民法院管辖第一审民事案件标准

2021.09.26

SPC Adjusts Criteria for the Jurisdiction of Intermediate People's Courts over Civil Cases of First Instance

日前，最高人民法院发出《关于调整中级人民法院管辖第一审民事案件标准的通知》（下称《通知》），自 10 月 1 日起实施。

The Supreme People's Court ("SPC") has issued the Circular on Adjusting the *Criteria for the Jurisdiction of Intermediate People's Courts over Civil Cases of First Instance* (the "*Circular*"), effective from October 1, 2021.

《通知》规定：一、当事人住所地均在或者均不在受理法院所处省级行政辖区的，中级人民法院管辖诉讼标的额 5 亿元以上的第一审民事案件。二、当事人一方住所地不在受理法院所处省级行政辖区的，中级人民法院管辖诉讼标的额 1 亿元以上的第一审民事案件。三、战区军事法院、总直属军事法院管辖诉讼标的额 1 亿元以上的第一审民事案件。四、对新类型、疑难复杂或者具有普遍法律适用指导意义的案件，可以依照民事诉讼法第三十八条的规定，由上级人民法院决定由其审理，或者根据下级人民法院报请决定由其审理。

The *Circular* makes clear: (1) in the event that the domiciles of both parties are or are not within the provincial-level jurisdiction where the accepting court is located, the intermediate people's court will have jurisdiction over the first-instance civil cases with the amount of subject matter of action of not less than RMB 500 million; (2) in the event that the domicile of either of the parties is not within the provincial-level jurisdiction where the accepting court is located, the intermediate people's court will have jurisdiction over the first-instance civil cases with the amount of subject matter of action of not less than RMB 100 million; (3) theaters' military courts and the military court directly under the People's Liberation Army will have jurisdiction over the first-instance civil cases with the amount of subject matter of action of not less than RMB 100 million; (4) Cases of new types, complicated cases, or cases with guiding



Shanghai CILS® Law Firm
上海信石®律师事务所

Room 2615, Enterprise Square
No. 228 Meiyuan Road, Shanghai 200070
People's Republic of China

中国上海市梅园路 228 号
企业广场 2615 室, 邮编: 200070

Tel: +86 21 80127725
Fax: +86 21 80127724
www.cilslaw.com

significance in universal application of law may be tried by the people's court at a higher level in accordance with Article 38 of the *Civil Procedure Law*, or by the people's court at a lower level for upon request and approval.

(Source: <http://www.court.gov.cn/fabu-xiangqing-324151.html>)

三、市场监管总局就修改《电子商务法》征求意见

2021.09.01

SAMR Proposes to Amend the E-Commerce Law

近日，国家市场监督管理总局起草了《关于修改〈中华人民共和国电子商务法〉的决定（征求意见稿）》（下称《征求意见稿》），现向社会征求意见，意见反馈截止于 10 月 14 日。

The State Administration for Market Regulation ("SAMR") has recently released the *Decision to Amend the E-Commerce Law of the People's Republic of China (Draft for Comment)* (the "Draft") to solicit public comments. The deadline for submitting feedbacks is October 14, 2021.

《征求意见稿》拟对《电子商务法》第四十三条、第八十四条作出修改，具体修改内容涉及四个方面，包括延长反通知后等待期，将原规定修改为“电子商务平台经营者在转送声明到达知识产权权利人后二十个工作日内，未收到权利人已经投诉或者起诉通知的，应当及时终止所采取的措施。”同时，为了缓和反通知等待期过长带来的可能的交易损失问题，增加一款规定：平台内经营者提出担保，用于赔偿潜在的知识产权侵权所造成的损失的，则电子商务平台经营者可以暂时中止所采取的措施。

The Draft proposes to amend Articles 43 and 84 of the *E-Commerce Law* in specifically four aspects, including extending the waiting period after the giving of a counter-notice by amending the original provision to read: "the e-commerce platform operator shall lift the measures taken if it does not receive a notice within 20 business days after the transferred statement reaches the intellectual property right owner notifying that a



Shanghai CILS® Law Firm
上海信石®律师事务所

Room 2615, Enterprise Square
No. 228 Meiyuan Road, Shanghai 200070
People's Republic of China

中国上海市梅园路 228 号
企业广场 2615 室, 邮编: 200070

Tel: +86 21 80127725
Fax: +86 21 80127724
www.cilslaw.com

compliant or lawsuit has been lodged by the right owner." Meanwhile, a provision is added to mitigate any transaction losses that may be caused by such a long waiting period, which reads: the e-commerce platform operator may suspend the measures taken if the alleged infringing operator on the platform provides a security for the compensation for any losses that may be caused by the potential intellectual property infringement."

(Source: http://www.samr.gov.cn/hd/zjdc/202108/t20210831_334252.html)

四、最高法院启动四级法院审级职能定位改革试点

2021.09.28

SPC Launches Pilot Reform on Defining Trial Level Functions under the Four-tiered Court System

近日，最高人民法院发布《关于完善四级法院审级职能定位改革试点的实施办法》（下称《办法》），自 2021 年 10 月 1 日起施行。

The Supreme People's Court ("SPC") has recently released the *Implementing Measures for Improving the Pilot Reform on Defining Trial Level Functions under the Four-tiered Court System* (the "*Measures*") for implementation from October 1, 2021.

《办法》标志着为期 2 年的试点工作正式启动。《办法》共 23 条，其内容包括五个方面：一是明确四级法院审级职能定位。二是完善行政案件级别管辖制度。三是完善案件提级管辖机制。四是改革再审程序。五是完善最高法院审判权力运行机制。

Marking the official launch of a two-year pilot program, the *Measures* consist of 23 articles mainly in five aspects: (1) defining trial level functions under the four-tiered court system; (2) improving the hierarchy-based jurisdiction of civil and administrative cases; (3) improving the mechanism for bringing cases to the higher-level courts for jurisdiction; (4) reforming retrial procedures; (5) improving the SPC's trial power operation mechanism.



Shanghai CILS® Law Firm
上海信石®律师事务所

Room 2615, Enterprise Square
No. 228 Meiyuan Road, Shanghai 200070
People's Republic of China

中国上海市梅园路 228 号
企业广场 2615 室, 邮编: 200070

Tel: +86 21 80127725
Fax: +86 21 80127724
www.cilslaw.com

其中,《办法》明确了四级法院审级职能定位,即基层人民法院重在准确查明事实、实质化解纠纷;中级人民法院重在二审有效终审、精准定分止争;高级人民法院重在再审依法纠错、统一裁判尺度;最高人民法院监督指导全国审判工作、确保法律正确统一适用。

Among others, the *Measures* specify the trial level functions under the four-tiered court system. In brief, grass-roots people's courts shall focus on accurately ascertaining facts and substantively resolving disputes; intermediate people's courts shall focus on effectively rendering final trial in second instance, precisely determining the key aspects and ending the disputes; high people's courts shall focus on correcting errors in accordance with the law in retrials and unifying judgment standards; the SPC shall supervise and guide the trial work nationwide to ensure the correct and uniform application of law.

(Source: <http://www.court.gov.cn/fabu-xiangqing-324681.html>)

本期编辑:
Author:

Chenwei Bao
Tel: 86-21-80127725
Email: wendy.bao@cilslaw.com

This publication is for informational purpose only. It does not cover every aspect of the topics with which it deals. It should not be construed or relied on as legal advice or to create a lawyer-client relationship. For any further legal advice, please contact us.

Shanghai CILS® Law Firm, a partnership registered at Room 2615, Enterprise Square, No. 228 Meiyuan Road, Shanghai, PRC.

CILS® 2021