

ບົດແປບໍ່ເປັນທາງການ

ນະຄອນຫຼວງວຽງຈັນ, ວັນທີ 5 ມິຖຸນາ 2020

ເລກທີ 094

ເຖິງ: ຫ້ອງການ ກະຊວງອຸດສາຫະກຳ ແລະ ການຄ້າ ລາວ.

ເລື່ອງ: ແຈ້ງບັນຊີລາຍຊື່ຂອງບໍລິສັດ ສປ ຈີນທີ່ມີຄຸນວຸດທິໃນການສົ່ງອອກເຄື່ອງອຸປະກອນ

ການແພດ.



ສຳນັກງານທີ່ປຶກສາດ້ານເສດຖະກິດ-ການຄ້າ ສະຖານທູດ ສປ ຈີນ ປະຈຳ ສປປ ລາວ ຂໍຖືເປັນກຽດແຈ້ງມາຍັງທ່ານຊາບວ່າ: ເພື່ອຕັ້ງໜ້າສະໜັບສະໜູນສັງຄົມສາກົນຕ້ານພະຍາດໂຄວິດ-19, ກະຊວງການຄ້າ, ອົງການກົມໃຫຍ່ພາສີ, ອົງການກວດກາ ແລະ ຄຸ້ມຄອງຢາແຫ່ງຊາດ ຈີນໄດ້ຮ່ວມກັນອອກແຈ້ງການເລກທີ 5 ກ່ຽວກັບດຳເນີນການສົ່ງອອກເຄື່ອງອຸປະກອນການແພດເປັນລະບຽບຮຽບຮ້ອຍ ແລະ ແຈ້ງການເລກທີ 12 ກ່ຽວກັບເພີ່ມທະວີການຕິດຕາມກວດກາຄຸນນະພາບຂອງເຄື່ອງອຸປະກອນການແພດທີ່ສົ່ງອອກຕໍ່ມອີກ. ອົງການກວດກາ ແລະ ຄຸ້ມຄອງຢາແຫ່ງຊາດ ຈີນໄດ້ຄັດອອກກົດໝາຍ, ລະບຽນການຕ່າງໆກ່ຽວກັບມາດຕະການ, ການຍືນຍັງ, ການກວດກາເຄື່ອງອຸປະກອນການແພດ ແລະ ຂໍ້ມູນການຈົດທະບຽນຂອງຜະລິດຕະພັນດັ່ງກ່າວ (ເອກະສານຊ້ອນທ້າຍ). ຖ້າຫາກວ່າຝ່າວລາວຕ້ອງການສົ່ງຊື້ເຄື່ອງອຸປະກອນການແພດເພື່ອຕ້ານພະຍາດໂຄວິດ-19, ໃຫ້ເລືອກເອົາບັນດາບໍລິສັດຈີນທີ່ມີຄຸນວຸດທິໃນການສົ່ງອອກເຄື່ອງດັ່ງກ່າວ. ບັນຊີລາຍຊື່ບໍລິສັດ ສປ ຈີນທີ່ມີຄຸນວຸດທິໃນການຜະລິດຜ້າອັດປາກ-ດັງປະເພດບໍ່ແມ່ນໃຊ້ໃນການແພດ ແລະ ໄດ້ຮັບການຮັບຮອງມາດຕະຖານສາກົນ ຫຼື ໄດ້ຈົດທະບຽນເຊິ່ງໄດ້ຮັບການຍືນຍັນຈາກກະຊວງການຄ້າຈີນເຊິນເຂົ້າໃນເວັບໄຊ: www.cccmhpie.org.cn (ອັບເດດຂໍ້ມູນປະຈຳ).

ຜູ້ປະສານງານສະຖານທູດ ສປ ຈີນ: ທ້າວ ແກ້ວປະເສີດ 020-55561735.

ສະຖານທູດ ສປ ຈີນ ປະຈຳ ສປປ ລາວ
ສຳນັກງານທີ່ປຶກສາດ້ານເສດຖະກິດ-ການຄ້າ

中华人民共和国驻老挝人民民主共和国
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老挝工贸部
办公厅

中华人民共和国驻老挝人民民主共和国大使馆经商处向老挝工贸部办公厅致意并荣幸地通报如下：为积极支持国际社会抗击新冠肺炎，中国商务部、海关总署、国家药品监督管理局发布了“2020年第5号关于有序开展医疗物资出口的公告”和“2020年第12号关于进一步加强防疫物资出口质量监管的公告”。中国国家市场监督管理总局整理了中方防疫物资标准、认证、检验检测等方面的法律法规及产品注册认证等相关材料（材料附后），如老方需从中国采购医疗防护物资，请老方从中方提供的有资质出口企业名单中进行采购。商务部确认取得国外标准认证或注册的非医用口罩生产企业清单网址：www.cccmhpie.org.cn动态更新。

中国大使馆经商处联系人：李能斌，电话：55561735。

顺致崇高敬意！



Laws and Regulations related to Epidemic Prevention and Control Supplies and Registration Information of Medical Devices

1. Laws and regulations related to epidemic prevention and control supplies, the texts of which may be accessed through the listed links.

(1) Standardization Law of the People's Republic of China

Relevant articles:

Article 2 Mandatory standards must be implemented. The State shall encourage the adoption of voluntary standards.

Article 25 Products and services that do not meet mandatory standards shall not be manufactured, sold, imported or provided.

Article 26 Technical requirements for export products and services shall be in accordance with contractual obligations.

<http://www.sac.gov.cn/sbgs/flfg/fl/bzhf/201803/t20180323342012.htm>

(2) Regulations of the People's Republic of China on Certification and Accreditation

Chapter III and Chapter VI of the *Regulations of the People's Republic of China on Certification and Accreditation* concerning the engagement of certification activities and the legal liability for violation of certification activities are related to the certification of epidemic prevention products.

<http://search.chinalaw.gov.cn/law/searchTitleDetail?LawID=334109&Query=%E8%AE%A4%E8%AF%81%E8%AE%A4%E5%8F%AF%E6%9D%A1%E4%BE%8B&IsExact=>

http://gkml.samr.gov.cn/nsjg/rzjcs/201902/t20190215_2822

66.html

(3) Regulations for the Supervision and Administration of Medical Devices

According to the *Regulations for the Supervision and Administration of Medical Devices* and related rules and regulations, China classifies medical devices including in vitro diagnostic reagents into three categories according to risk levels. Medical masks and protective clothing are regulated according to the standards for Class II medical devices. Goggles and face shields are regulated according to the standards for Class I medical devices in China. Medical ventilators are regulated according to the standards for Class II and Class III medical devices. Medical thermometers are regulated according to the standards for Class II medical devices.

<http://search.chinalaw.gov.cn/law/searchTitleDetail?LawID=403329&Query=%E5%8C%BB%E7%96%97%E5%99%A8%E6%A2%B0&IsExact=>

<http://www.nmpa.gov.cn/WS04/CL2076/331389.html>

2. Information of standards of epidemic prevention products, including Chinese national standards list of epidemic prevention products, comparison information of Chinese and foreign standards related to epidemic prevention products, list of Chinese national standards in foreign language related to epidemic prevention products, and equivalence of standards information regarding face masks issued by foreign countries. The web link is:

<http://www.sac.gov.cn/sacen/FAC/>

3. Registration information of medical devices in China. The web link is:

<http://www.nmpa.gov.cn/WS04/CL2582/>

4. Regulatory requirements and standards for coronavirus

reagent test kits and protective equipment in China. The web links are:

http://english.nmpa.gov.cn/2020-03/30/c_467202.htm?from=singlemessage&isappinstalled=0

5. Certification guide for export of masks and other epidemic prevention products to the European Union and the United States, including the directory of domestic certification bodies with qualifications related to masks and other epidemic prevention products as Notified Bodies of EU. The web links are:

http://www.cnca.gov.cn/xxgk/hydt/202004/t20200404_58016.shtml

http://www.cnca.gov.cn/xxgk/hydt/202004/t20200415_58103.shtml

6. Qualification verification is required for medical devices and protection equipment inspection bodies and testing laboratories according to Article 57 of the *Regulations for the Supervision and Administration of Medical Devices* and Article 16 of the *Regulations of the People's Republic of China on Certification and Accreditation*.

The directory of inspection and testing organizations for medical devices and protection equipment with national qualification verification can be accessed through the following web link.

http://www.samr.gov.cn/xw/zj/202002/t20200207_311208.html