



中华人民共和国商务部

MINISTRY OF COMMERCE OF THE PEOPLE'S REPUBLIC OF CHINA

商务部 海关总署 国家药品监督管理局公告 2020 年第 5 号 关于有序开展医疗物资出口的公告

Order No. 5, 2020: Announcement on Orderly Export of Medical Materials, by the Ministry of Commerce, the General Administration of Customs, and National Medical Products Administration of the People's Republic of China

当前，全球疫情呈加速扩散蔓延态势。在做好自身疫情防控的基础上，有序开展医疗物资出口是深化疫情防控国际合作、共同应对全球公共卫生危机的重要举措。在疫情防控特殊时期，为有效支持全球抗击疫情，保证产品质量安全、规范出口秩序，自 4 月 1 日起，出口新型冠状病毒检测试剂、医用口罩、医用防护服、呼吸机、红外体温计的企业向海关报关时，须提供书面或电子声明（模版见附件 1），承诺出口产品已取得我国医疗器械产品注册证书（相关注册信息见附件 2），符合进口国（地区）的质量标准要求。海关凭药品监督管理部门批准的医疗器械产品注册证书验放。上述医疗物资出口质量监管措施将视疫情发展情况动态调整。

At present, the global pandemic spread is accelerating. On the basis of doing a good job of preventing and controlling the spread of the Covid-19 epidemic in China, orderly export of medical materials is an important measure to deepen the international cooperation in the pandemic prevention and control and jointly respond to this global public health crisis. In this extraordinary time, to effectively support the global fight against the Covid-19 pandemic, ensure product quality and safety and orderly export, enterprises which export novel coronavirus test reagents, surgical masks, medical protective gowns, respirators and infrared thermometers shall provide written or electronic statements (see Annex 1 for the template), and shall promise that the export-bounding products have obtained the Medical Device Product Registration Certificate of China (see Annex 2 for relevant registration information) and have met the quality standard requirements of the importing countries (regions), when declaring to the Customs, since April 1, 2020. The Customs shall examine and release the medical materials according to the Medical Device Product Registration Certificates granted by departments under the National Medical Products Administration. The aforementioned supervision measures for the export quality of medical materials will be dynamically adjusted according to the development of the

pandemic.

有关医疗物资出口企业要确保产品质量安全、符合相关标准要求，积极支持国际社会共同抗击疫情。

Relevant medical materials exporting enterprises should ensure the quality and safety of their products, meet the requirements of relevant standards, and actively support the international community in the fight against the Covid-19 pandemic.

商务部 海关总署 国家药品监督管理局

The Ministry of Commerce, the General Administration of Customs, and National Medical Products
Administration of the People's Republic of China

2020 年 3 月 31 日

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