Guidance for Exporting PPE/Medical Devices from China to the UK

Frequently Asked Questions

1. What are the implications of GACC No.53 announcement (see Annex 2)?

The products that fall under the 11 categories of medical devices in the announcement are subject to intensified commodity inspection. Inevitably this will slow down customs procedures.

However, customs are allowing inspection to be done at the place of export, rather than at the place of production as usual. They have also waived the requirement to obtain an electronic account before customs declaration, which is normally required for products subject to commodity inspection.

2. What do Chinese customs officials do during commodity inspection?

Commodity inspection usually includes but is not limited to the following types of inspections:

- Inspect to see if the products match with medical device registration certificate;
- Inspect to see if the products' packaging, label, name and quantity match with customs declaration;
- Inspect product safety and quality statement and testing reports submitted by the company
- Inspect the quality of the product and sample for laboratory testing if necessary

3. How do I know if a product is a medical device or not?

It depends on whether the standards that the product adheres to is a medical device standard. For example, if a mask is compliant with EU medical mask standard EN14683 then it is a medical device. If a mask is compliant with EU PPE standard EN149 then it is not a medical device. It does not matter whether it will be used by medical professionals in the UK. GACC Commodity Inspection Department lists and regularly updates standards for medical / non-medical devices in China and the EU. Please see the link below http://sjs.customs.gov.cn/sjs/zcfg56/index.html (Chinese only).

4. If a product is not a medical device, but falls under the same HS code as 11 categories of medical devices regulated by the No.53 announcement, would commodity inspection be required?

No. No.53 announcement only applies to medical devices under the 11 categories.

5. How do I know if a Chinese medical device's registration certificate from national or provincial Medical Products Administration is authentic or not?

This can be checked via

http://app1.nmpa.gov.cn/datasearchcnda/face3/dir.html?type=ylqx (Chinese only) by inputting product information such as registration number, name of the manufacturer, etc.

6. How do I know the classification, i.e. type 2 or type 3, for a medical device?
Medical device classification catalogue can be checked via http://app1.nmpa.gov.cn/datasearchcnda/face3/dir.html?type=ylqx (Chinese only)

7. How do I know if a CE certificate is authentic or not?

First, check whether the certification body is a notified body in the following EU database:
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main
Second, if it is in the above database, check whether its certification scope cover the product.
Third, contact the notified body directly using the contact details shown in the database to confirm the validity of the certificate.

8. Can a trader export medical devices without a medical device business record or license?

According to SFDA 2017 No.37 Decree ‘administrative measures for medical device business supervision and management', which is regulating business activities such as purchase, storage, and sales of medical device, unless the trader is also the manufacturer and sell products directly from home or from the production site, a medical device business record (for type 2 medical device) or license (for type 3 medical device) is required to export medical device.

Annex 1 - Checklist of certifications for Chinese manufacturers/traders supplying PPE/medical devices to the UK

Masks/口罩

1. Production license/生产许可
2. Medical device registration certificate which is listed at the NMPA website http://www.nmpa.gov.cn/WS04/CL2582/ (non-medical masks don't require this)/国家药监局网站 http://www.nmpa.gov.cn/WS04/CL2582/ 可查的医疗器械注册证书（非医用口罩不需要）
3. Product testing report/产品检测报告
4. Business license/营业执照
5. Product quality and safety statement/产品质量安全承诺书
6. Medical device business record (non-medical masks don't require this)/医疗器械经营备案（非医用口罩不需要）
7. Declaration for exporting medical products (non-medical masks don't require this)/出口医疗物资声明（非医用口罩不需要）
8. CE certification/CE 认证
9. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
10. In the case that the seller is a trader rather than the manufacturer; and that the product falls into the category of type 2 and type 3 medical device, apart from above listed documents, it must have relevant medical device business record or license/若卖方是贸易企业而不是生产企业，且产品属于二类或三类医疗器械，除了提供上述材料，还须具备相应的医疗器械经营备案或许可资质。
11. Commodity Inspection from customs of place of export for medical products fall under HS code 6307900010/海关商品编号 6307900010 项下的医疗物资须经出口地海关法检
12. Imported COVID19 testing kits, medical masks, medical gowns, ventilators and infrared thermometer currently cannot be exported/进口的新型冠状病毒检测试剂、医用口罩、医用防护服、呼吸机、红外体温计目前无法出口

Disinfectant/消毒液

1. Production license/生产许可
2. Product testing report/产品检测报告
3. Product quality and safety statement/产品质量安全承诺书
4. Business license/营业执照
5. Undenatured ethyl alcohol of an alcoholic strength by volume of 80% vol or higher requires export permit issued by an agency under MOFCOM/酒精浓度 80%以上的未改性乙醇须向商务部授权的发证机关申请两用物项和技术出口许可证
6. Conformity statement for manufacturers exporting dangerous chemicals/出口危险性化学品生产企业符合性声明
7. Exporting dangerous goods packaging performance testing report/出境危险货物包装容器性能检验结果单

8. Certificate of hazard classification and identification for chemicals/危险特性分类鉴别报告
9. Safety data and hazard labelling sample/安全数据单、危险公示标签样本
10. If inhibitor or stabilizer is required to be added, need to provide explanation on name and quantity of the inhibitor or stabilizer/对需要添加抑制剂或稳定剂的产品，应提供实际添加抑制剂或稳定剂的名称数量等情况说明
11. DGM or SRICI certificate for safe air transport of goods (alcoholic strength must meet airline's requirements as well)/DGM 或上化院航空运输条件鉴别报告书（酒精浓度还须符合航空公司要求）
12. CE certification/CE 认证
13. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
14. Commodity Inspection from customs of place of export for medical products fall under HS code 3808940010/海关商品编号 3808940010 项下的医疗物资须经出口地海关法检

Gown/防护服

1. Production license/生产许可
2. Medical device registration certificate which is listed at the NMPA website http://www.nmpa.gov.cn/WS04/CL2582/ (non-medical gowns don't require this)/国家药监局网站 http://www.nmpa.gov.cn/WS04/CL2582/ 可查的医疗器械注册证书（非医用防护服不需要）
3. Product testing report/产品检测报告
4. Product quality and safety statement/产品质量安全承诺书
5. Medical device business record (non-medical gowns don't require this)/医疗器械经营备案（非医用防护服不需要）
6. Business license/营业执照
7. Declaration for exporting medical products (non-medical gowns don't require this)/出口医疗物资声明（非医用防护服不需要）
8. CE certification/CE 认证
9. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
10. In the case that the seller is a trader rather than the manufacturer; and that the product falls into the category of type 2 and type 3 medical device, apart from above listed documents, it must have relevant medical device business record or license/若卖方是贸易企业而不是生产企业，且产品属于二类或三类医疗器械，除了提供上述材料，还须具备相应的医疗器械经营备案或许可资质。
11. Commodity Inspection from customs of place of export for medical products fall under HS code 6210103010, 3926209000/海关商品编号 6210103010, 3926209000 项下的医疗物资须经出口地海关法检
12. Imported COVID19 testing kits, medical masks, medical gowns, ventilators and infrared thermometer currently cannot be exported/进口的新型冠状病毒检测试剂、

医用口罩、医用防护服、呼吸机、红外体温计目前无法出口

Gloves/手套

1. Production license/生产许可
2. Product testing report/产品检测报告
3. Product quality and safety statement/产品质量安全承诺书
4. Business license/营业执照
5. Medical device business record (for certain medical gloves)/医疗器械经营备案（部分医用手套需要）
6. CE certification/CE 认证
7. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
8. In the case that the seller is a trader rather than the manufacturer; and that the product falls into the category of type 2 and type 3 medical device, apart from above listed documents, it must have relevant medical device business record or license/若卖方是贸易企业而不是生产企业，且产品属于二类或三类医疗器械，除了提供上述材料，还须具备相应的医疗器械经营备案或许可资质。
9. Commodity Inspection from customs of place of export for medical products fall under HS code 3926201100, 3926201900, 4015110000, 4015190000/海关商品编号 3926201100, 3926201900, 4015110000, 4015190000 项下的医疗物资须经出口地海关法检

Goggles/护目镜

1. Production license/生产许可
2. Product testing report/产品检测报告
3. Product quality and safety statement/产品质量安全承诺书
4. Business license/营业执照
5. CE certification/CE 认证
6. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
7. Commodity Inspection from customs of place of export for medical products fall under HS code 9004909000/海关商品编号 9004909000 项下的医疗物资须经出口地海关法检

Ventilator/呼吸机

1. Production license/生产许可
2. Medical device registration certificate which is listed at the NMPA website http://www.nmpa.gov.cn/WS04/CL2582/ /国家药监局网站可查的医疗器械注册证书 http://www.nmpa.gov.cn/WS04/CL2582/
3. Product testing report/产品检测报告
4. Product quality and safety statement/产品质量安全承诺书

5. Business license/营业执照
6. Medical device business license or record/医疗器械经营许可证或备案
7. Declaration for exporting medical products/出口医疗物资声明
8. Battery test report (if contains battery)/电池测试报告（如有电池）
9. DGM or SRICI certificate for safe air transport of goods/ DGM 或上化院航空运输条件鉴别报告书
10. CE certification/CE 认证
11. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
12. In the case that the seller is a trader rather than the manufacturer; and that the product falls into the category of type 2 and type 3 medical device, apart from above listed documents, it must have relevant medical device business registration or license/若卖方是贸易企业而不是生产企业，且产品属于二类或三类医疗器械，除了提供上述材料，还须具备相应的医疗器械经营备案或许可资质。
13. Imported COVID19 testing kits, medical masks, medical gowns, ventilators and infrared thermometer currently cannot be exported/进口的新型冠状病毒检测试剂、医用口罩、医用防护服、呼吸机、红外体温计目前无法出口
14. Commodity Inspection from customs of place of export for medical products fall under HS code 9019200010, 9019200090/ 海关商品编号 9019200010, 9019200090 项下的医疗物资须经出口地海关法检

COVID19 Testing kits/新冠病毒检测试剂盒

1. Special permit from provincial medical products management administration or special goods export/import permit by customs/省级药监部门出具的特别批准文件或海关出入境特殊物品卫生检疫审批
2. Production license/生产许可
3. Medical device registration certificate which is listed at the NMPA website http://www.nmpa.gov.cn/WS04/CL2582/ /国家药监局网站可查的医疗器械注册证书 http://www.nmpa.gov.cn/WS04/CL2582/
4. Product testing report/产品检测报告
5. Product quality and safety statement/产品质量安全承诺书
6. Business license/营业执照
7. Medical device business license or record/医疗器械经营许可证或备案
8. Declaration for exporting medical products/出口医疗物资声明
9. DGM or SRICI certificate for safe air transport of goods/ DGM 或上化院航空运输条件鉴别报告书
10. CE certification/CE 认证
11. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
12. In the case that the seller is a trader rather than the manufacturer; and that the product falls into the category of type 2 and type 3 medical device, apart from above listed documents, it must have relevant medical device business record or

license/若卖方是贸易企业而不是生产企业，且产品属于二类或三类医疗器械，除了提供上述材料，还须具备相应的医疗器械经营备案或许可资质。

13. Imported COVID19 testing kits, medical masks, medical gowns, ventilators and infrared thermometer currently cannot be exported/进口的新型冠状病毒检测试剂、医用口罩、医用防护服、呼吸机、红外体温计目前无法出口
14. Electronic account acquired after passing customs health quarantine/海关卫生检疫合格后获得的电子底账
15. Export sales certificate/药监局出口销售证明

Syringe pump and infusion pump/注射泵和输液泵

1. Production license/生产许可
2. Medical device registration certificate/药监局医疗器械注册证书
3. Product testing report/产品检测报告
4. Product quality and safety statement/产品质量安全承诺书
5. Business license/营业执照
6. Medical device business license or record/医疗器械经营许可证或备案
7. Battery test report (if contains battery)/电池测试报告（如有电池）
8. DGM or SRICI certificate for safe air transport of goods/ DGM 或上化院航空运输条件鉴别报告书
9. CE certification/CE 认证
10. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
11. In the case that the seller is a trader rather than the manufacturer; and that the product falls into the category of type 2 and type 3 medical device, apart from above listed documents, it must have relevant medical device business record or license/若卖方是贸易企业而不是生产企业，且产品属于二类或三类医疗器械，除了提供上述材料，还须具备相应的医疗器械经营备案或许可资质。

Ventilator consumables (breathing filters, circuits, masks, humidifiers, peep valves, etc.)/呼吸机耗材（呼吸过滤器、呼吸管路、呼吸面罩、湿化器、呼吸限压阀等）

1. Production license/生产许可
2. Medical device registration certificate/药监局医疗器械注册证书
3. Product testing report/产品检测报告
4. Product quality and safety statement/产品质量安全承诺书
5. Business license/营业执照
6. Medical device business license or record/医疗器械经营许可证或备案
7. CE certification/CE 认证
8. Import and export license. (If the manufacturer doesn't have it, it should use a trade agent who has it.)/进出口权（无进出口权生产企业应找有进出口权的外贸代理）
9. In the case that the seller is a trader rather than the manufacturer; and that the product falls into the category of type 2 and type 3 medical device, apart from

above listed documents, it must have relevant medical device business record or license/若卖方是贸易企业而不是生产企业，且产品属于二类或三类医疗器械，除了提供上述材料，还须具备相应的医疗器械经营备案或许可资质。

Annex 2 - General Administration of Customs of the People's Republic of China Announcement No. 53 in 2020

In order to strengthen the supervision of the export quality of medical materials, the General Administration of Customs has decided to carry out the export commodity inspection of medical materials (see the annex for details) under the "63079000000" and other codes from the date of this announcement in accordance with the law of inspection of import and export commodities and its implementing regulations.
It is hereby announced.

Attachment: Announcement attachment

General Administration of Customs
April 10, 2020

Attachment:

No.	Type	HS codes
1	masks for medical use	6307900010
2	protective apparel for medical use	6210103010
		3926209000
3	infrared thermometer	9025199010
4	ventilator	9019200010
		9019200090
5	caps for medical use	6505009900
6	googles for medical use	9004909000
7	gloves for medical use	3926201100
		3926201900
		4015110000
		4015190000
8	shoe covers for medical use	6307900090
		3926909090

		4016999090
9	patient monitor machine	9018193010
10	sanitising wipes for medical use	3005901000
		3005909000
11	sanitiser for medical use	3808940010

Annex 3 - Joint MOFCOM, GACC, NMPA Announcement on Orderly Export of Medical Supplies No. 5 [2020]

At present, the global epidemic is accelerating its spread. On the basis of doing well in epidemic prevention and control, orderly export of medical materials is an important measure to deepen international cooperation in epidemic prevention and control and jointly respond to the global public health crisis. Amid the special period of epidemic, in order to effectively support the global fight against disease, ensure product quality and safety, and standardize export order, from April 1, when exporting test reagents, medical masks, medical protective clothing, respirators, infrared thermometers, companies shall provide written or electronic statements declaring the export products have obtained China's medical device registration certificates and meet the quality standard requirements of the importing country or region. The Customs shall examine and release the medical devices with the registration certificate approved by the drug regulatory department. The above-mentioned measures for quality supervision of export medical materials will be dynamically adjusted according to the development of the epidemic situation.

Relevant medical material export enterprises should ensure the quality and safety of their products and meet the requirements of relevant standards, and actively support the international community in fighting against the epidemic.