Checklist of certifications for Chinese manufacturers supplying medical products to the UK/输英中国医疗物资生产企业证书自查表

Masks/口罩

- 1. Production license/生产许可
- 2. Medical equipment registration certificate (non-medical masks don't require this)/ 药监局医疗器械注册证书(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 certificate/产品质量安全书
- 6. Medical equipment business registration (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)

Disinfection gel/消毒液

- 1. Production license/生产许可
- 2. Product testing report/产品检测报告
- 3. Product quality certificate/产品质量安全书
- 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)

Gown/防护服

- 1. Production license/生产许可
- 2. Medical equipment registration certificate (non-medical gowns don't require this)/ 药局监医疗器械注册证书(非医用防护服不需要)
- 3. Product testing report/产品检测报告
- 4. Product quality certificate/产品质量安全书
- 5. Medical equipment business registration (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)

Gloves/手套

- 1. Production license/生产许可
- 2. Product testing report/产品检测报告
- 3. Product quality certificate/产品质量安全书
- 4. Business license/营业执照
- 5. Medical equipment business registration (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)

Goggles/护目镜

- 1. Production license/生产许可
- 2. Product testing report/产品检测报告
- 3. Product quality certificate/产品质量安全书
- 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)

Ventilator/呼吸机

- 1. Production license/生产许可
- 2. Medical equipment 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 certificate/产品质量安全书
- 5. Business license/营业执照
- 6. Medical equipment business license or registration/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)

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 equipment registration certificate /药监局医疗器械注册证书
- 4. Product testing report/产品检测报告
- 5. Product quality certificate/产品质量安全书
- 6. Business license/营业执照
- 7. Medical equipment business license or registration/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)

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

- 1. Production license/生产许可
- 2. Medical equipment 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 certificate/产品质量安全书
- 5. Business license/营业执照
- 6. Medical equipment business license or registration/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)