

# CMD 认证业务范围

## CMD Certification Business Scope

### 一、 管理体系认证领域 **Management system certification area**

1. 质量管理体系（GB/T 19001-2016 idt ISO 9001:2015）  
Quality Management System (GB/T 19001-2016 idt ISO 9001:2015)
2. 环境管理体系（GB/T 24001-2016 idt ISO 14001:2015）  
Environmental Management System (GB/T 24001-2016 idt ISO 14001:2015)
3. 职业健康安全管理体系（GB/T 45001-2020 idt ISO 45001:2018）  
Occupational Health and Safety Management System (GB/T 45001-2020 idt ISO 45001:2018)
4. 医疗器械质量管理体系（GB/T 42061-2022 idt ISO 13485:2016）  
Medical Device-Quality Management System-Requirement for regulatory purposes (GB/T 42061-2022 idt ISO 13485:2016)
5. 医疗器械风险管理体系（YY/T 0316-2016 idt ISO 14971:2007（更正版）和/或 GB/T 42062-2022 idt ISO 14971:2019）  
Medical devices—Application of risk management to medical devices (YY/T 0316-2016 idt ISO 14971:2007 (revised) / GB/T 42062-2022 idt ISO 14971:2019)

### 二、 产品认证领域 **Product certification area**

- 17 仪器设备  
Instrument and equipment

### 三、 服务认证领域

#### **Service certification area**

- 03 批发业和零售业服务  
Wholesale and retail services
- 05 运输服务（陆路运输服务、水运服务、空运服务、支持性和辅助运输服务）  
Transport services (land transport services, water transport services,

air transport services, support and ancillary transport services)

15 保养和修理服务

Maintenance and repair services

#### 四、质量管理体系已获 CNAS 认证的认可业务范围

CNAS accredited quality management system certification business scope

- 12 化学品、化学制品及纤维  
12 Chemicals, chemical products and fibres
- 13.02 药品制剂的制造  
13.02 Manufacture of pharmaceutical preparations
- 14 橡胶和塑料制品  
14 Rubber and plastic products
- 17 基础金属及金属制品  
17 Basic metals and fabricated metal products
- 18 机械及设备（武器、弹药、军用战车制造除外）  
18 Machinery and equipment
- 19 电和光学设备  
19 Electrical and optical equipment
- 23.06 医疗及牙科器械和用品的制造  
23.06 Manufacture of medical and dental instruments and supplies
- 29 批发及零售  
29 Wholesale and retail trade
- 33 信息技术  
33 Information technology
- 36 公共行政管理  
36 Public administration
- 38 健康和社会服务  
38 Health and social work

其中 of which:

- ◇ 13.02 中类 “13.02.00 药物制剂的制造”，按照医疗器械的预期用途及定义等进行小类划分，分为：

For middle category 13.02, "13.02.00 Manufacturing of pharmaceutical preparations", according to the intended use and definition of medical devices, are divided into the following subcategories:

- ✓ 13.02.00B 无源类医疗器械 passive medical devices
- ✓ 13.02.00C 无菌类医疗器械 sterile medical devices
- ✓ 13.02.00D 植入类医疗器械 Implantation medical devices
- ✓ 13.02.00E 试剂类医疗器械 reagent medical devices

- ◇ 23.06 中类 “23.06.00 医疗及牙科器械和用品的制造”，按照医疗器械的预期用途和定义进行小类划分，分为：

For middle category 23.06, "23.06 Manufacture of medical and dental instruments and supplies", according to the intended use and definition of medical devices, are divided into the following subcategories:

- ✓ 23.06.00A 有源类医疗器械 active medical devices
- ✓ 23.06.00B 无源类医疗器械 passive medical devices
- ✓ 23.06.00C 无菌类医疗器械 sterile medical devices
- ✓ 23.06.00D 植入类医疗器械 Implantation medical devices

## 五、 产品认证已获 CNAS 认可业务范围：

CNAS accredited product certification business scope

19.11.00 医疗、外科以及整形外科器械的制造

19.11.00 Manufacture of medical, surgical, and orthopedic instruments

481 医疗器械 medical devices:

- 4811 使用 x 射线或  $\alpha$ 、 $\beta$  或  $\gamma$  射线以及中子、质子、介子及其他粒子辐射为主的医用射线设备；

4811 Medical radiological equipment that uses X-rays or  $\alpha$ 、 $\beta$ 、 $\gamma$  rays, as well as neutron, proton, meson, and other particle radiation.

4812 内科、外科、牙科或兽医用的电子诊断设备，紫外线、红外线设备和激光设备；医用光学仪器，医用内窥镜；临床检验体外诊断系统；医用体外循环设备及血液净化设备；

4812 Electronic diagnostic equipment for medical, surgical, dental or veterinary use ; Ultraviolet, infrared and laser equipment ; Medical optical instrument, medical endoscope ; Clinical test in vitro diagnostic system ; Medical extracorporeal circulation equipment and blood purification equipment.

- 4813 口腔科（牙科）用的其他仪器设备和器具（注射器、注射针和类似品除外）；

4813 Other instruments and apparatus for stomatology (dentistry) (except syringes, hypodermic needles and the like).

- 4814 内科、外科或实验室等医用消毒灭菌设备及器具；

4814 Medical disinfection and sterilization equipment and utensils such as medicine, surgery or laboratory.

- 4815 内科、外科或兽医等医用其他器械；

4815 Other instruments for medical, surgical or veterinary purposes.

- 4816 机械疗法仪器设备；按摩仪器设备；心理功能测验装置；臭氧治疗器、氧气治疗器、喷雾治疗器、人工呼吸器或其他治疗用呼吸器具等物理治疗仪器设备；美容器械；其他呼吸器具和防毒面具；

4816 Apparatus and equipment for mechanical therapy; apparatus and equipment for massage; apparatus and equipment for psychological function tests; apparatus and equipment for physiotherapy, such as ozone therapies, oxygen therapies, spray therapies, artificial respirators or other respiratory appliances for therapeutic use; cosmetology apparatus; other respiratory appliances and gas masks.

- 4817 矫形用手术器械及器具；夹板和其他骨折结合器具；人造的人体部分；助听器和为弥补生理缺陷或残疾而穿戴或携带或植入人体内的其

他器具；

4817 Surgical instruments and appliances for orthopedic purposes; splints and other appliances for the union of fractures; artificial human body parts; hearing aids and other appliances worn or carried for the purpose of remedying physical defects or disabilities or implanted in the human body.

- 4818 内科、外科、牙科或兽医用的医用家具等通用设备及专用诊疗台床；有旋转、倾斜、升降装置的理发椅和类似的椅子；医用材料；外科植入物用材料。

4818 General-purpose equipment such as medical furniture for medical, surgical, dental or veterinary use and specialized diagnostic and treatment tables and beds; barber's chairs and similar chairs with swivel, tilt and lift mechanisms; medical materials; materials for surgical implants.

- ◇ 按照医疗器械的预期用途和定义进行小类划分，分为：

According to the intended use and definition of medical devices, subcategories are divided into:

- ✓ 481A 有源类医疗器械 active medical devices
- ✓ 481B 无源类医疗器械 passive medical devices
- ✓ 481C 无菌类医疗器械 sterile medical device
- ✓ 481D 植入类医疗器械 sterile medical device

## 六、 环境管理体系认证已获 CNAS 认可业务范围

CNAS accredited Environmental management system certification business scope

- 13.02 药品制剂的制造（部分）  
13.02 Manufacture of pharmaceutical preparations (in part)
- 17 基础金属及金属制品（部分）  
17 Basic metals and fabricated metal products (in part)
- 18 机械及设备（部分）  
18 Machinery and equipment (in part)

- 19 电和光学设备（部分）  
19 Electrical and optical equipment (in part)
- 23.06 医疗及牙科器械和用品的制造  
23.06 Manufacture of medical and dental instruments and supplies
- 29 批发及零售（部分）  
29 Wholesale and retail trade (in part)

七、 职业健康安全管理体系认证已获 CNAS 认可业务范围：

CNAS accredited Occupational health and safety management system certification business scope

- 13.02 药品制剂的制造（部分）  
13.02 Manufacture of pharmaceutical preparations (in part)
- 17 基础金属及金属制品（部分）  
17 Basic metals and fabricated metal products (in part)
- 18 机械及设备（部分）  
18 Machinery and equipment (in part)
- 19 电和光学设备（部分）  
19 Electrical and optical equipment (in part)
- 23.06 医疗及牙科器械和用品的制造  
23.06 Manufacture of medical and dental instruments and supplies  
(in part)
- 29 批发及零售（部分）  
29 Wholesale and retail trade (in part)