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 (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 Risk management System（YY/T 0316-2016 idt ISO 14971:2007（revised）/ GB/T 42062-2022 idt ISO 14971:2019）

6. 医疗器械上市后风险管理体系认证 (GB/T 42062-2022 idt ISO 14971:2019)

   Post-market Risk Management System for Medical Devices (GB/T 42062-2022 idt ISO 14971:2019)

7. 信息安全管理体系（ISO/IEC 27001:2022）

   Information Security Management System (ISO/IEC 27001:2022)

8. 建筑工程质量管理体系（GB/T19001-2016/ISO9001:2015 + GB/T 50430-2007）

   Construction Engineering Quality Management System (GB/T19001-2016/ISO9001:2015 + GB/T 50430-2007)

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 non-active 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 Implantable medical devices
  - ✓ 13.02.00E 试剂类医疗器械 IVD 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 non-active 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 Implantable 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α、β 或γ 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 α 、 β 、γ 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 non-active medical devices
- ✓ 481C 无菌类医疗器械 sterile medical device
- ✓ 481D 植入类医疗器械 implantable medical devices

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)
- 14 橡胶和塑料制品

  14 Rubber and plastic products
- 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)
- 33 信息技术

  33 Information technology

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)
- 14 橡胶和塑料制品

  14 Rubber and plastic products

- 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)

- 33 信息技术

  33 Information technology

八、医疗器械质量管理体系认证已获 IAS 认可业务范围：

IAS accredited MDQMS business scope:

主要技术领域/技术领域 **Main Technical Areas/Technical Areas**	
A.1.1 – 无源医疗器械 Table A.1.1 – Non-Active Medical Devices	一般无源、非植入医疗器械 General non-active, Non-implantable medical devices
	无源植入医疗器械 Non-active implantable medical devices
	伤口护理器械 Devices for wound care
	无源牙科器械及附件 Non-active dental devices and accessories
	上述未列明的无源医疗器械 Non-active medical devices other than specified above
A.1.4 – 体外诊断医疗器械 Table A.1.4 - In Vitro Diagnostic Medical Devices	用于临床化学、免疫化学（免疫学）、血液学/ 止血学/免疫血液学、微生物学、感染免疫学、组织学/细胞学、基因检测的试剂、试剂产品、校

	准品和质控品 Reagents and reagent products, calibrators, and control materials for:Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
	体外诊断仪器及软件 IVD Instruments and software
	上述未列明的体外诊断医疗器械 IVD medical devices other than specified above