

# ISO 9001 (GB/T19001) 质量管理体系申请认证须知信息

## ISO 9001 (GB/T 19001) Quality Management System Certification Application Information

### 一、可开展业务范围及认可范围

#### Business scope available and accreditation scope

##### (一) 质量管理体系 (认证依据: GB/T 19001-2016/ISO 9001:2015)

##### Quality Management System (certification basis: GB/T 19001-2016/ISO 9001:2015)

序号 No.	大类与范围 Major category and scope	状态 Status	CNAS 认可 CNAS accreditation	IAS 认可 IAS accreditation
1	01 农业、林业和渔业 Agriculture, forestry and fishing	开展 Available		全部 All
2	02 采矿业和采石业 Mining and quarrying	开展 Available		全部 All
3	03 食品、饮料和烟草 Food, beverages and tobacco	开展 Available		全部 All
4	04 纺织品及纺织制品 Textiles and textile products	开展 Available		全部 All
5	05 皮革及皮革制品 Leather and leather products	开展 Available		全部 All
6	06 木材及木制品 Wood and wood products	开展 Available		全部 All
7	07 纸浆、纸及纸制品 Pulp, paper and paper products	开展 Available		全部 All
8	08 出版业 Publishing	暂不开展 Not available		全部 All
9	09 印刷业 Printing	开展 Available		全部 All
10	10 焦炭及精炼石油产品的制造 Manufacture of coke and refined petroleum products	开展 Available		
11	11 核燃料 Nuclear fuel	暂不开展 Not available		
12	12 化学品、化学产品及纤维 Chemicals, chemical products and fibres	开展 Available		
13	13 药品 Pharmaceuticals	开展 Available		
14	14 橡胶和塑料制品 Rubber and plastic products	开展 Available	全部 All	全部 All
15	15 非金属矿物制品 Non-metallic mineral products	开展 Available		全部 All
16	16 混凝土、水泥、石灰、石膏及其他 Concrete, cement, lime, plaster and others	开展 Available		全部 All
17	17 基础金属及金属制品 Basic metals and fabricated metal products	开展 Available		全部 All
18	18 机械及设备 Machinery and equipment	开展 Available		全部 All
19	19 电和光学设备 Electrical and optical equipment	开展 Available	全部 All	全部 All

20	20 造船业 Shipbuilding	开展 Available	全部 All	全部 All
21	21 航空航天 Aerospace	开展 Available	全部 All	
22	22 其他运输设备 Other transport equipment	开展 Available		全部 All
23	23 其他未另分类制造业 Other manufacturing not elsewhere classified	开展 Available		全部 All
24	24 回收业 Recycling	开展 Available		全部 All
25	25 供电业 Electricity supply	开展 Available		
26	26 供气业 Gas supply	暂不开展 Not available		
27	27 供水业 Water supply	开展 Available		
28	28 建筑业 Construction	开展 Available		全部 All
29	29 批发和零售业；汽车、摩托、个人及家庭用品修理业 Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods	开展 Available	全部 All	全部 All
30	30 宾馆及餐馆 Hotels and restaurants	开展 Available		全部 All
31	31 运输、仓储和通信业 Transport, storage and communication	开展 Available		全部 All
32	32 金融中介、房地产和租赁 Financial intermediation, real estate and rental	开展 Available	全部 All	全部 All
33	33 信息技术 Information technology	开展 Available	全部 All	全部 All
34	34 工程服务 Engineering services	开展 Available		全部 All
35	35 其他服务 Other services	开展 Available	全部 All	全部 All
36	36 公共行政管理 Public administration	开展 Available	全部 All	全部 All
37	37 教育 Education	开展 Available	全部 All	全部 All
38	38 健康和社会工作 Health and social work	开展 Available		
39	39 其他社会服务 Other social services	开展 Available		全部 All

## (二) 工程建设施工企业质量管理体系 (认证依据: GB/T 19001-2016/ISO 9001:2015 & GB/T 50430-2017)

### Quality management system for engineering construction enterprises (certification basis: GB/T 19001-2016/ISO 9001:2015 & GB/T 50430-2017)

大类 Major category	中类 Intermediate category	小类 Subcategory	内容 Content	状态 Status
28			建筑业 Construction	可开展 Available
			建设项目的开发 Development of construction projects	可开展 Available
	28.01	28.01.00	建设项目的开发 Development of construction projects	可开展 Available

28.02		住宅及非住宅建筑的建设 Construction of residential and non-residential buildings	可开展 Available
	28.02.00	住宅及非住宅建筑的建设 Construction of residential and non-residential buildings	可开展 Available
28.03	28.03.01	公路建设 Road construction	可开展 Available
	28.03.02	铁路建设 Railway construction	可开展 Available
	28.03.03	桥梁和隧道的建设 Construction of bridges and tunnels	可开展 Available
28.04		公用设施项目的建设 Construction of utility projects	可开展 Available
	28.04.01	市政公用工程建设 Municipal public works construction	可开展 Available
		市政公用工程建设 Municipal public works construction	可开展 Available
		园林绿化及景观工程施工（不含养护） Landscaping and landscape engineering construction (excluding maintenance)	可开展 Available
	28.04.02	电力和电信用公用设施项目的建设 Construction of utility projects for electricity and telecommunications	可开展 Available
		电力工程建设 Electric power engineering construction	可开展 Available
		通信工程建设 Communication engineering construction	可开展 Available
28.05		其他土木工程项目的建设 Construction of other civil engineering projects	可开展 Available
	28.05.01	水利工程建设 Construction of water conservancy projects	可开展 Available
		港口与航道工程建设 Port and waterway engineering construction	可开展 Available
		水利水电工程建设 Water conservancy and hydropower engineering construction	Available
	28.05.02	其他未另分类的土木工程项目的建设 Construction of other civil engineering projects not elsewhere classified	可开展 Available
		矿山工程建设 Mining engineering construction	可开展 Available
		冶金工程建设 Metallurgical engineering construction	可开展 Available
28.06		室外运动设施的建造 Construction of outdoor sports facilities	可开展 Available
		拆除及场地准备 Demolition and site preparation	可开展 Available
	28.06.01	拆除 Demolition	可开展 Available
	28.06.02	场地准备 Site preparation	可开展 Available

		28.06.03	钻孔和钻探测试 Drilling and 钻探 testing	可开展 Available
	28.07		电气、管道和其他建筑安装活动 Electrical, plumbing and other construction installation activities	可开展 Available
		28.07.01	电气安装 Electrical installation	可开展 Available
		28.07.02	管道、供暖和空调系统的安装 Installation of plumbing, heating and air conditioning systems	可开展 Available
		28.07.03	其他建筑安装 Other construction installation	可开展 Available
			石油化工工程建设 Petrochemical engineering construction	可开展 Available
			机电工程建设 Mechanical and electrical engineering construction	可开展 Available
			起重设备安装 Lifting equipment installation	可开展 Available
	28.08		建筑装修和装饰 Building finishing and decoration	可开展 Available
		28.08.01	抹灰 Plastering	可开展 Available
		28.08.02	木工安装 Carpentry installation	可开展 Available
		28.08.03	地面和墙壁覆盖 Floor and wall covering	可开展 Available
		28.08.04	涂装和玻璃安装 Painting and glazing	可开展 Available
		28.08.05	其他建筑装修和装饰 Other building finishing and decoration	可开展 Available
	28.09		其他专业建筑活动 Other specialised construction activities	可开展 Available
		28.09.01	屋顶工程 Roofing works	可开展 Available
		28.09.02	其他未另分类的专业建筑活动包含但不限于：核工程施工、特种工程施工、地基基础工程施工 Other specialised construction activities not elsewhere classified including but not limited to: nuclear engineering construction, special engineering construction, foundation engineering construction)	可开展 Available
			特种工程 Special engineering	可开展 Available
			地基基础工程（包括打桩） Foundation engineering (including piling)	可开展 Available
			劳务分包 Labour subcontracting	可开展 Available
			设备租赁（配备操作员） Equipment rental (with operator)	可开展 Available
			防水、防腐工程 Waterproofing and anti-corrosion engineering	可开展 Available

## (三) 医疗器械质量管理体系 (认证依据: GB/T 42061-2022/ISO 13485:2016)

## Medical devices quality management system (certification basis: GB/T 42061-2022/ISO 13485:2016)

主技术领域 Main technical field	技术领域 Technical field	状态 Status
MD01 非有源医疗设备 Non-active medical devices	MD01.01 一般非有源, 非植入 General non-active, non-implantable	可开展 Available
	MD01.02 非有源植入物 Non-active implants	可开展 Available
	MD01.03 伤口护理设备 Wound care devices	可开展 Available
	MD01.04 非有源牙科设备及其配件 Non-active dental devices and accessories	可开展 Available
	MD01.05 牙科植入物 Dental implants	暂不开展 Not available
	MD01.06 其他非有源医疗器械 Other non-active medical devices	可开展 Available
MD02 有源性 (非植入式) 医疗器械 Active (non-implantable) medical devices	MD02.01 一般有源性医疗器械 General active medical devices	可开展 Available
	MD02.02 软件 Software	可开展 Available
	MD02.03 成像设备 Imaging equipment	可开展 Available
	MD02.04 监控设备 Monitoring equipment	可开展 Available
	MD02.05 放射治疗和热疗设备 Radiotherapy and hyperthermia equipment	可开展 Available
	MD02.06 其他有源性设备 (非植入) Other active devices (non-implantable)	可开展 Available
MD04 体外诊断医疗器械 In vitro diagnostic medical devices	MD04.01 试剂和试剂产品, 校准和控制材料 Reagents and reagent products, calibration and control materials	可开展 Available
	MD04.02 体外诊断仪器和软件 In vitro diagnostic instruments and software	可开展 Available
	MD04.03 其他体外诊断医疗器械 Other in vitro diagnostic medical devices	可开展 Available
MD07 部件和服务 Components and services	MD07.01 原材料 Raw materials	可开展 Available
	MD07.02 零部件 Components and parts	可开展 Available
	MD07.03 半成品 Semi-finished products	可开展 Available
	MD07.05 分销服务 Distribution services	可开展 Available
	MD07.06 维护服务 Maintenance services	可开展 Available
	MD07.07 运输服务 Transport services	可开展 Available
	MD07.08 其他服务 Other services	可开展 Available

无分包境外认证机构业务。

No subcontracting of business to overseas certification bodies.

## 二、认证依据标准 **Certification basis standards**

本机构依据以下国家标准开展质量管理体系认证活动：

This organization carries out quality management system certification activities based on the following national standards:

- GB/T 19001-2016/ISO 9001:2015 《质量管理体系要求》
  - GB/T 19001-2016/ISO 9001:2015 "Quality management systems Requirements"
- 对工程建设施工企业，同时依据 GB/T 50430-2017 《工程建设施工企业质量管理规范》
  - For engineering construction enterprises, also based on GB/T 50430-2017 "Code for quality management of engineering construction enterprises"
- 医疗器械领域质量认证依据 GB/T 42061-2022/ISO 13485:2016 《医疗器械 质量管理体系用于法规的要求》
  - For quality certification in the medical devices field, based on GB/T 42061-2022/ISO 13485:2016 "Medical devices - Quality management systems - Requirements for regulatory purposes"

认证活动同时遵循 CNAS-CC01 《合格评定 管理体系审核认证机构的要求》（等同采用 ISO/IEC 17021-1）、《质量管理体系认证规则》及相关法律法规要求。

Certification activities also comply with CNAS-CC01 "Requirements for bodies providing audit and certification of management systems" (identical adoption of ISO/IEC 17021-1), the "Quality Management System Certification Rules" and relevant legal and regulatory requirements.

## 三、认证方案 **Certification scheme**

(一) 质量管理体系（认证依据：GB/T 19001-2016/ISO 9001:2015）执行《质量管理体系认证规则》（CNCA-QMS-01:2025）；

Quality management system (certification basis: GB/T 19001-2016/ISO 9001:2015) follows the "Quality Management System Certification Rules" (CNCA-QMS-01:2025);

(二) 工程建设施工企业质量管理体系（认证依据：GB/T 19001-2016/ISO 9001:2015& GB/T 50430-2017）执行 CILQC GZ-48 《工程建设施工企业质量管理体系认证规则》；

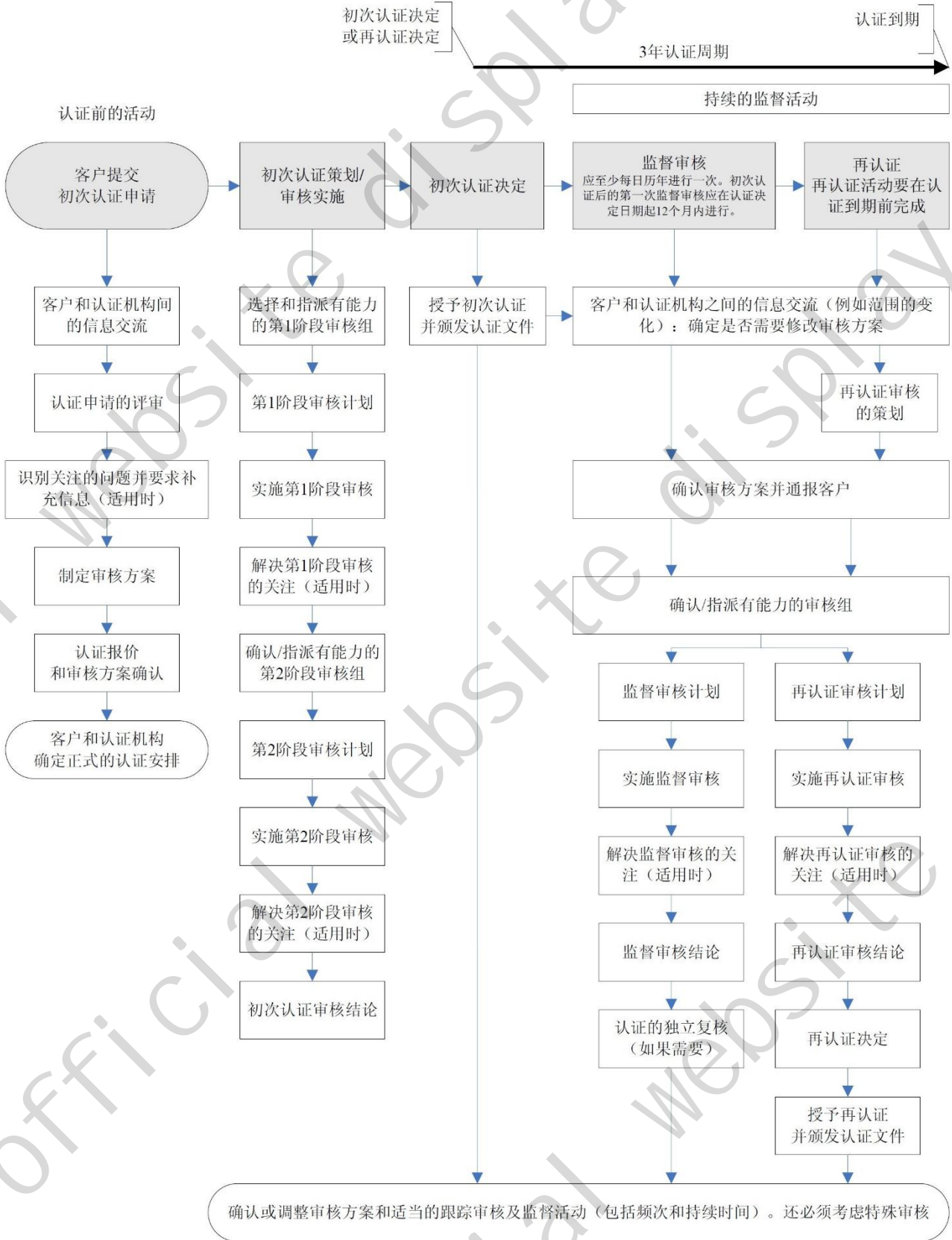
Quality management system for engineering construction enterprises (certification basis: GB/T 19001-2016/ISO 9001:2015 & GB/T 50430-2017) follows CILQC GZ-48 "Certification Rules for Quality Management Systems of Engineering Construction Enterprises";

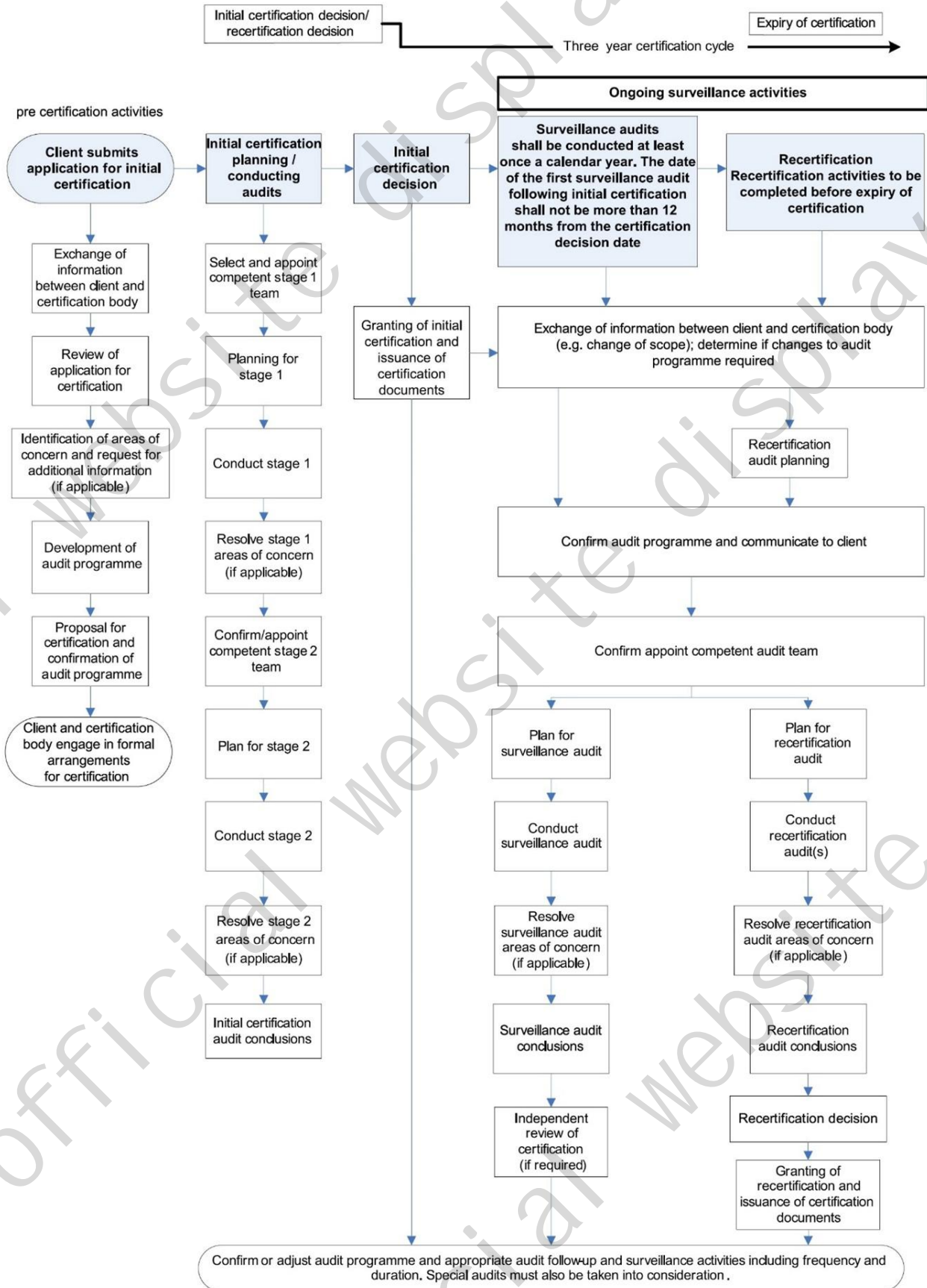
(三) 医疗器械质量管理体系（认证依据：GB/T 42061-2022/ISO 13485:2016）执行 CILQC GZ-05 《医疗器械质量管理体系认证规则》。

Medical devices quality management system (certification basis: GB/T 42061-2022/ISO 13485:2016) follows CILQC GZ-05 "Certification Rules for Medical Devices Quality Management Systems".

## 四、认证流程 **Certification process**

见下图所示。As shown in the figure below.





## 五、授予、拒绝、保持、更新、暂停（恢复）、注销、撤销认证证书以及扩大或缩小认证范围的程序规定 **Procedural provisions for granting, refusing, maintaining, updating, suspending (reinstating), cancelling, withdrawing certification certificates and extending or reducing certification scope**

详细内容见公开文件 Ti PD08 《授予/批准、拒绝、保持、更新、变更、暂停、恢复、注销、撤销认证证书或扩大、缩小认证范围的规定与程序》。

See public document Ti PD08 "Provisions and Procedures for Granting/Approving, Refusing, Maintaining, Updating, Changing, Suspending, Reinstating, Cancelling, Withdrawing Certification Certificates or Extending or Reducing Certification Scope" for details.

## 六、拟向认证委托人获取的信息 **Information to be obtained from the certification client**

为完成认证审核，本机构将至少获取以下必要信息：

To complete the certification audit, this organization will obtain at least the following necessary information:

- 组织基本信息（名称、地址、法律地位等）；

Basic information of the organization (name, address, legal status, etc.);

- 质量管理体系文件；

Quality management system documentation;

- 内部审核、管理评审记录；

Internal audit and management review records;

- 质量管理体系运行三个月以上的客观证据；

Objective evidence that the quality management system has been in operation for more than three months;

- 多场所组织的各场所详情（地址、人员、范围等）；

- Details of each site of a multi-site organization (address, personnel, scope, etc.);

- 法律法规符合性声明及相关资质证明；

Statement of conformity with legal and regulatory requirements and relevant qualification evidence;

- 认证范围内涉及的许可、资质文件；

Licenses and qualification documents involved within the certification scope;

- 体系删减情况说明（如适用）；

Explanation of system exclusions (if applicable);

- 申请前一年内发生质量事故、与质量有关的行政处罚、认证范围内的产品发生产品质量国家监督抽查不合格或其他质量抽查不合格的，整改完毕的书面结论。（如有）

If quality accidents, quality-related administrative penalties, failure of products within the certification scope in national supervision and spot-checks for product quality or other quality spot-checks have occurred within one year before the application, the written conclusion stating that corrective actions have been completed (if any).

## 七、保密规定 **Confidentiality provisions**

本机构郑重承诺：This organization hereby solemnly undertakes:

- 对认证委托人所提供的信息严格保密；

To strictly keep confidential all information provided by the certification client;

- 除法律法规或认证认可规范要求外，未经委托人书面同意，不向任何第三方披露其非公开信息；

Except as required by laws, regulations or certification and accreditation norms, not to disclose its non-public information to any third party without the written consent of the client;

- 所有审核人员均签署保密协议，履行保密义务。

All audit personnel have signed confidentiality agreements and fulfil their confidentiality obligations.

## 八、认证收费标准 **Certification fee standards**

详细内容见公开文件 Ti PD02 《认证收费标准及说明》。

See public document Ti PD02 "Certification Fee Standards and Explanations" for details.

## 九、认证证书、认证标志及相关的规定 **Provisions for the use of certification certificates, certification marks and related matters**

详细内容见公开文件 Ti PD05 《认证证书、标志使用规则》。

See public document Ti PD05 "Rules for the Use of Certification Certificates and Marks" for details.

## 十、对认证过程和结果的申诉、投诉规定 **Provisions for appeals and complaints regarding the certification process and results**

详细内容见公开文件 Ti PD07 《对索要信息的请求、申诉、投诉和争议处理规定》。

See public document Ti PD07 "Provisions for Handling Requests for Information, Appeals, Complaints and Disputes" for details.

## 十一、提前较短时间通知的审核情形 **Audit scenarios with short notice**

例如在下列情况下，本机构可能实施提前较短时间通知的审核：

For example, this organization may implement audits with short notice in the following circumstances:

- 接到涉及管理体系严重不符合的投诉或举报；

Receiving a complaint or report involving a major nonconformity of the management system;

- 获证组织发生突发环境事件；

The certified organization experiencing an environmental emergency;

- 法律法规或行业监管要求；

Requirements of laws, regulations or industry supervision;

- 组织发生影响管理体系的重大变更（如结构、流程、范围等）；

The organization undergoing major changes affecting the management system (e.g., structure, processes, scope, etc.);

- 对被暂停的认证资格进行追踪；

Following up on suspended certification status;

- 其他可能影响认证决定的紧急情况。

Other emergencies that may affect the certification decision.

此类审核旨在确保认证的公正性、有效性和证书的持续可信度。

Such audits aim to ensure the impartiality and effectiveness of certification and the continued credibility of the certificate.

## 十二、查询与联系 **Enquiries and contact**

最新认证政策及公开文件要求请查阅本机构官方网站：

For the latest certification policies and public document requirements, please refer to this organization's official website:

**[www.titcgroup.com](http://www.titcgroup.com)**

如有疑问，请联系您的认证经理或本机构客户服务部门。

If you have any questions, please contact your certification manager or this organization's customer service department.