

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 8631 Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	BCC Inc.	
	Issue No: 013 Issue date: 04 February 2022	
	11/FL, Building 1 Guoyingyuan Xicheng District Beijing PR China 100035	Contact: Shi Jingwei Tel: +86-10-58561816 Fax: +86 -10-58561801 Email: ukas.latd@bcc.com.cn Website: www.bcc.com.cn

SUMMARY OF ACCREDITED SCOPE

Accredited to provide certification of the following Management Systems Standards and related Sector Schemes as detailed in this schedule:

- [Quality Management Systems \(QMS\) to ISO 9001: 2015](#)
- [Medical Devices - Quality Management Systems \(MD-QMS\) to ISO 13485: 2016](#)



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KEY LOCATION ADDRESS	QMS	MD-QMS
11/FL, Building 1, Guoyingyuan, Xicheng District, Beijing PR China 100035	✓	✓

This Certification Body has demonstrated to UKAS that it has the systems and processes in place to provide the competence and capability, including understanding of local requirements, to manage and issue accredited management systems certification in the country in which it is established and in any other country, for the standards and scopes detailed on this schedule, unless specifically detailed in the individual Management System scope table (*denoted by **).



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QUALITY MANAGEMENT SYSTEMS

In accordance with ISO/IEC 17021-1: 2015

ISO 9001: 2015 Certification

Accreditation Scope Reference (as defined in IAF ID 1)	Full / Limited Accreditation	Extent of Scope
IAF 3 Food products, beverages and tobacco	Full	
IAF 4 Textiles and textile products	Full	
IAF 12 Chemicals, chemical products and fibres	Full	
IAF 14 Rubber and plastic products	Full	
IAF 15 Non-metallic mineral products	Full	
IAF 16 Concrete, cement, lime, plaster etc	Full	
IAF 17 Basic metals and fabricated metal products	Full	
IAF 18 Machinery and equipment	Full	
IAF 19 Electrical and optical equipment	Full	
IAF 29 Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	Full	
IAF 32 Financial intermediation; real estate; renting	Full	

END



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MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

In accordance with ISO/IEC 17021-1: 2015

ISO 13485: 2016 Certification

IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area
1.1 Non-active Medical Devices	General non-active, non-implantable medical devices
	Non-active implants
	Devices for wound care
	Non-active dental devices and accessories
1.2 Active Medical Devices (Non-Implantable)	General active medical devices
	Monitoring devices
	Devices for radiation therapy and thermo therapy
1.4 In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> • Clinical Chemistry • Immunochemistry (immunology) • Haematology /Haemostasis /Immunoematology • Microbiology • Infection Immunology • Histology/cytology • Genetic Testing
	In vitro diagnostic instruments and software
	IVD medical devices other than specified above



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MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

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ISO 13485: 2016 Certification

IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area
1.5 Sterilisation Method for Medical Devices	Ethylene oxide gas sterilisation (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilisation (e.g. gamma, x-ray, electron beam)
	Low temperature steam and formaldehyde sterilisation
	Thermic sterilisation with dry heat
	Sterilisation with hydrogen peroxide
	Sterilisation method other than specified above
1.7 Parts or Services	Raw materials
	Components
	Subassemblies
	Distribution services
	Maintenance services
	Transportation services
	Other services

END