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:** 015 **Issue date**: 23 July 2024	
Room 45-(05)-02 **Floor5** **No. 45, Guangqumennei Street,** **Dongcheng District,** **Beijing** **PR China** **100062**	**Contact: Xiaowei Zhang** **Tel: +86-10-58579318** **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:

- **Medical Devices - Quality Management Systems (MD-QMS) to ISO 13485: 2016**

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BCC Inc.

Issue No: 015 **Issue date:** 23 July 2024

KEY LOCATION ADDRESS	MD-QMS
Room 45-(05)-02 Floor 5, No. 45,Guangqumennei Street, Dongcheng District, Beijing, PR China 100062	✓

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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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: • Clinical Chemistry • Immunochemistry (immunology) • Haematology /Haemostasis /Immunohematology • Microbiology • Infection Immunology • Histology/cytology • Genetic Testing
	In vitro diagnostic instruments and software

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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
	IVD medical devices other than specified above
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

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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**
	Other services

END