

Date

Reference

2024-09-30

2024/631

Scope of accreditation

Certification of management system according to SS-EN ISO/IEC 17021-1:2015

Intertek Medical Notified Body AB

Kista

Accreditation number

10426

A014254-001

Accreditation areas and requirement specifications/standards

<i>Accreditation area</i>	<i>Requirement specification</i>
Medical devices management system	SS-EN ISO 13485:2016

Medical devices management system

<i>Main Technical Area (IAF MD8 Annex 1)</i>	<i>Technical Area (IAF MD8 Annex 1)</i>
1.1 Non-active Medical Devices	Devices for wound care
	General non-active, non-implantable medical devices
	Non-active dental devices and Accessories
	Non-active implants
	Non-active medical devices other than specified above
1.2 Active Medical Devices (Non-Implantable)	Devices for imaging
	Devices for radiation therapy and thermo therapy
	General active medical devices
	Monitoring devices
	Active (non-implantable) medical devices other than specified above
1.5 Sterilization Method for Medical Devices	Aseptic processing

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1.5 Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)
	Low temperature steam and formaldehyde sterilization
	Moist heat
	Radiation sterilization (e.g. gamma, X-ray, electron beam)
	Sterilization with hydrogen peroxide
	Thermic sterilization with dry heat
	Sterilization method other than specified above
1.6 Devices incorporating/Utilizing Specific Substances/ Technologies	Medical devices incorporating derivates of human blood
	Medical devices incorporating medicinal substances
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
	Medical devices utilizing micromechanics
	Medical devices utilizing nanomaterials
	Medical devices utilizing tissues of animal origin
	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above
1.7 Parts or services	Calibration services
	Components
	Distribution services
	Maintenance services
	Raw materials
	Subassemblies
	Transportation services
	Other services

Changes in the scope of accreditation are in bold.

The accreditation also applies to the corresponding version of the international EN and ISO standards.