SWEDAC
Styrelsen för ackreditering och teknisk kontroll
Swedish Board for Accreditation and Conformity Assessment

Appendix 1

Date 2024-03-22

Reference 2024/2487

Scope of accreditation

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

RISE Medical Notified Body AB | Kista | Accreditation number 10597

A015347-001

Accreditation areas and requirement specifications/standards

Accreditation area	*Requirement specification*
Medical devices management system	SS-EN ISO 13485:2016

Medical devices management system

Main Technical Area (IAF MD8 Annex 1)	*Technical Area (IAF MD8 Annex 1)*
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 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**
	Ethylene oxide gas sterilization (EOG)

1.5 Sterilization Method for Medical Devices	**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
1.7 Parts or 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.