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

Appendix 2

Date	Case number
2019-11-19	2018/250

Scope of accreditation

Intertek Semko AB

Accreditation number	1003
NB 0413	A000426-002

93/42/EEC

Decision	*Product family*	*Product*	*Intended use*	*Modul*
	Horizontal notification	MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery		
		MDS 7006 - Medical devices in sterile condition		
	Medical devices	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI

	Medical devices	MD 0103 - Non-active orthopaedic and rehabilitation	EC declaration of conformity (production quality assurance)	Annex V
		MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI

	Medical devices	MD 0108 - Non-active medical devices for disinfecting, cleanin	EC declaration of conformity (production quality assurance)	Annex V
		MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI

	Medical devices	MD 0302 - Suture material and clamps	EC declaration of conformity (production quality assurance)	Annex V
		MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI

	Medical devices	MD 1101 - Devices for extra-corporal circulation, infusion an	EC declaration of conformity (production quality assurance)	Annex V
		MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI

	Medical devices	MD 1106 - Active dental devices	EC declaration of conformity (production quality assurance)	Annex V
		MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1111 - Software	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI

	Medical devices	MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (production quality assurance)	Annex V
		MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI
			EC declaration of conformity (production quality assurance)	Annex V
		MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system)	Annex II
			EC declaration of conformity (product quality assurance)	Annex VI

	Medical devices	MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (production quality assurance)	Annex V

Changes in the scope of accreditation are in bold. MD codes according to NBOG 2009-3