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

Appendix 1

Date	Case number
2021-05-04	2019/2811

Scope of accreditation

Notified body according to SS-EN ISO/IEC 17021-1:2015

Accreditation number	1002
NB 0402	A002626-033

RISE Research Institutes of Sweden AB

93/42/EEC

Product family, product/ Intended use/ Product Range	***Product***	***Procedure/Modules***	***Annexes or articles of the directive***	***Note***
Horizontal notification	MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
Horizontal notification	MDS 7006 - Medical devices in sterile condition			
Horizontal notification	MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Medical devices	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system)	Annex II	

Medical devices	MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0106 - Non-active instruments	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0106 - Non-active instruments	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system)	Annex II	

Medical devices	MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system)	Annex II	Bone-anchored implant for dental and cranio-facial reconstruction
Medical devices	MD 0203 - Non-active functional implants	EC declaration of conformity (product quality assurance)	Annex VI	Bone-anchored implant for dental and cranio-facial reconstruction
Medical devices	MD 0203 - Non-active functional implants	EC declaration of conformity (production quality assurance)	Annex V	Bone-anchored implant for dental and cranio-facial reconstruction
Medical devices	MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0301 - Bandages and wound dressings	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0301 - Bandages and wound dressings	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0303 - Other medical devices for wound care	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0303 - Other medical devices for wound care	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system)	Annex II	

Medical devices	MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 0402 - Dental materials	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 0402 - Dental materials	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system)	Annex II	Bone-anchored implant for dental and cranio-facial reconstruction
Medical devices	MD 0403 - Dental implants	EC declaration of conformity (product quality assurance)	Annex VI	Bone-anchored implant for dental and cranio-facial reconstruction
Medical devices	MD 0403 - Dental implants	EC declaration of conformity (production quality assurance)	Annex V	Bone-anchored implant for dental and cranio-facial reconstruction
Medical devices	MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (product quality assurance)	Annex VI	

Medical devices	MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1104 - Active surgical devices	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 1104 - Active surgical devices	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1106 - Active dental devices	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	
Medical devices	MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 1111 - Software	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1111 - Software	EC declaration of conformity (product quality assurance)	Annex VI	

Medical devices	MD 1111 - Software	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1201 - Imaging devices utilising ionizing radiation	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	
Medical devices	MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (production quality assurance)	Annex V	
Medical devices	MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system)	Annex II	
Medical devices	MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (product quality assurance)	Annex VI	
Medical devices	MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (production quality assurance)	Annex V	