

Date

Case number

2025-03-07

2024/2301

Scope of accreditation

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

Accreditation number

1002

RISE Research Institutes of Sweden AB

NB 0402

A015506-003

93/42/EEC

<i>Product family, product/ Intended use/ Product Range</i>	<i>Product</i>	<i>Procedure/Modules</i>	<i>Annexes or articles of the directive</i>	<i>Note</i>
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	

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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	

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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	

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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	

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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	

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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	