

ACCREDITATION SCHEME FOR CERTIFICATION BODIES



Schedule

DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem
The Netherlands

Certificate No : MDQMS-2023-08
Issue No : 2
Date : 9 December 2025
Expiry of Certificate : 29 November 2027
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Accreditation Field : Medical Devices Quality Management System

The accreditation covers the following scopes:

Main Technical Area(s)	Technical Area(s)
Non-Active Medical Devices	Non-active implants
	General non-active, non-implantable medical devices
Active Medical Devices (Non-Implantable)	Monitoring devices
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)
	Radiation sterilization (e.g. gamma, x-ray, electron beam)
	Sterilization method other than specified above
Devices Incorporating / Utilizing Specific Substances / Technologies	Medical devices incorporating medicinal substances
	Medical devices utilizing tissues of animal origin

**Supplementary criteria for
certification bodies:**

SAC CT 18 - SAC Criteria for Certification Bodies
(Medical Devices - Quality Management Systems)

Standard used for certification:

ISO 13485:2016 Medical devices – Quality management
systems – Requirements for regulatory purposes

**Foreign location with key
activities:**

Nil

**Country where certificates are
issued:**

Singapore and USA