

Schedule

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

Certificate No : MDQMS-2023-08
Issue No : 1
Date : 30 November 2023
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