



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

inomed Medizintechnik GmbH

Im Hausgrün 29
79312 Emmendingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Equipment and systems for neuromonitoring, diagnostic purposes, functional neurosurgery and pain treatment; disposable and reusable instruments and electrodes and Photoplethysmography sensors according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 055435 MR2

Certificate unique ID 170769596

Effective date 2020-06-29

Expiry date 2024-05-26

Frankfurt am Main 2020-06-29

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate

Certificate registration No.: 055435 MR2

Certificate unique ID: 170769596

Effective date: 2020-06-29

inomed Medizintechnik GmbH

Im Hausgrün 29
79312 Emmendingen
Germany

Device family	Device	Class
Equipment and systems for neuromonitoring, diagnostic purposes, functional neurosurgery and pain treatment	Neuromonitoring Systems	Ila/Ilb
	Neurostimulator Systems	Ilb
	Electrophysiologic Diagnostic Systems	Ila
	Cryo Systems	Ilb
	Micro Electrode Recording Systems	Ila
	Lesion Generators	Ilb
Disposable and reusable instruments and electrodes	Instruments and Electrodes for stimulation and recording	Ila/III
	Instruments and Electrodes for lesioning applications with accessories	Ila/Ilb/III
	Biopsy Instruments	III
	Stereotactic Systems and accessories	Im/Ila
	Sterile cables and adapters	Is
Photoplethysmography sensors	Photoplethysmography sensors	Ila