



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	170774583
Effective date	2020-06-29
Expiry date	2024-05-26
Frankfurt am Main	2020-06-29

DQS Medizinprodukte GmbH

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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: 170774583
Effective date: 2020-06-29



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