inomed

Intraoperative Neuromonitoring
Functional Neurosurgery
Pain Treatment
Neurological Diagnostics

LG1 & LG2
RF Lesion Generator

›› APPLICATION FIELDS:

- Chronic pain (head, back, extremities)
- Trigeminal neuralgia
- Stereotactically guided brain lesion

For all common applications in
›› pain treatment
›› functional neurosurgery

› RF Lesion Generators

The inomed radiofrequency (RF) lesion generators meet the most exacting requirements in terms of safety, precision and comfort of use. The RF devices support a large variety of instruments for pain and brain applications. They feature mono- and bipolar application modes. With the LG2 Lesion Generator, the combination of two monopolar electrodes for a bipolar application is possible.

Art. No. 261 000
LG1 RF Lesion Generator
1 channel RF output

Art. No. 262 000
LG2 RF Lesion Generator
2 channel RF output

›› FEATURES

- ›› Monopolar and bipolar electrode configuration
- ›› Continuous RF and pulsed RF modes
- ›› Direct nerve stimulation for motor and sensory nerve localisation
- ›› Temperature- and power-controlled RF output
- ›› Permanent temperature, impedance and power measurement
- ›› NEM (Neutral Electrode Contact Quality Monitoring)
- ›› Audio impedance: output of the impedance value as sound
- ›› LCD touch screen allows an intuitive workflow
- ›› Remote control for ease of use
- ›› Saving of up to 35 preset programmes
- ›› Compact and lightweight system design

› Accessories

PAIN TREATMENT

›› **RF cannulas**
> Straight, curved or for trigeminal neuralgia
> 50–150 mm, 17–22 G, 2 mm–15 mm active tip

›› **TC pain electrodes**
> Suitable for all inomed cannulas
> Reusable electrodes (30 times)
> Disposable electrodes

BRAIN LESION PROCEDURES

›› **TC brain electrodes**
> Compatible with RM, ZD or Leksell stereotactic frame
> Monopolar and bipolar
> Varying diameter and active tip size
> Reusable (30 times)

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Accessories for LG2

Electrodes and Fitting Cannulas for LG2
RF Cannulas and Disposable TC-Pain-Electrodes

RF Cannulas

Disposable TC-Pain-Electrodes

Art. no.	Cannulas (10 pcs)
240 100	Disposable cannula 22G x 50 x 4, isolated with mandrin
240 109	Disposable cannula 22G x 50 x 7, isolated with mandrin

Nr. 5.1.

Art. no.	Cannulas (10 pcs)
240 101	Disposable cannula 22G x 100 x 2, isolated with mandrin
240 102	Disposable cannula 22G x 100 x 5, isolated with mandrin
240 114	Disposable cannula 22G x 100 x 7, isolated with mandrin
240 106	Disposable cannula 22G x 100 x 10, isolated with mandrin
240 152	Disposable cannula 22G x 100 x 5, curved, isolated with mandrin
240 153	Disposable cannula 22G x 100 x 10, curved, isolated with mandrin
240 156	Disposable cannula 20G x 100 x 10, curved, sharp tip, isolated with mandrin
240 157	Disposable cannula 20G x 100 x 10, curved, blunt tip, isolated with mandrin
240 111	Disposable cannula 20G x 100 x 2, isolated with mandrin
240 110	Disposable cannula 20G x 100 x 5, isolated with mandrin
240 112	Disposable cannula 20G x 100 x 10, isolated with mandrin
240 120	Disposable cannula 17G x 100 x 2, isolated with mandrin
240 121	Disposable cannula 17G x 100 x 5, isolated with mandrin
240 122	Disposable cannula 17G x 100 x 7, isolated with mandrin
240 123	Disposable cannula 17G x 100 x 10, isolated with mandrin

Nr. 4.1.

Art. no.	Cannulas (10 pcs)
240 103	Disposable cannula 20G x 150 x 2, isolated with mandrin
240 104	Disposable cannula 20G x 150 x 5, isolated with mandrin
240 105	Disposable cannula 20G x 150 x 7, isolated with mandrin
240 107	Disposable cannula 20G x 150 x 15, isolated with mandrin
240 108	Disposable cannula 20G x 150 x 10, isolated with mandrin
240 154	Disposable cannula 20G x 150 x 5, curved, isolated with mandrin
240 155	Disposable cannula 20G x 150 x 10, curved, isolated with mandrin
240 158	Disposable cannula 20G x 150 x 10, curved, sharp tip, isolated with mandrin
240 159	Disposable cannula 20G x 150 x 10, curved, blunt tip, isolated with mandrin
240 140	Disposable cannula 18G x 115 x 2, isolated with mandrin
240 141	Disposable cannula 18G x 115 x 5, isolated with mandrin
240 142	Disposable cannula 18G x 115 x 7, isolated with mandrin
240 143	Disposable cannula 18G x 115 x 10, isolated with mandrin

Art. no.	Disposable TC-Pain-Electrodes (10 pcs)
260 007	Disposable TC-Pain-Electrode 50 mm for disposable cannulas with 50 mm working length • delivered sterile • single use • cable length 3m
260 012	Disposable TC-Pain-Electrode 100 mm for disposable cannulas with 100 mm working length • delivered sterile • single use • cable length 3m
260 017	Disposable TC-Pain-Electrode 150 mm for disposable cannulas with 150 mm working length • delivered sterile • single use • cable length 3m
260 127	Disposable TC-Trigeminus-Electrode for disposable cannulas with 115 mm working length • delivered sterile • single use • cable length 3m

Conversion table for cannulas ›› Gauge - mm

Gauge	22 G	20 G	18 G	17 G
mm	0,7	0,9	1,2	1,4

Connecting Cable for LG2

Art. no.	Connnecting Cable
262 008	TC cable for LG2 with 6-pole Redel connector grey and connector for disposable TC-Electrodes • delivered non sterile • wipe-disinfectable

Accessories for LG2

Neutral Surface Electrode for LG2

Art. no.	Neutral Surface Electrode
211 009	**Neutral surface electrode** adhesive for monopolar stimulation and coagulation applications • Single use
262 012	**Neutral surface split electrode** adhesive for monopolar stimulation and coagulation applications, contact impedance is permanently checked by LG2 • Single use
262 002	**Neutral cable** Cable 3 m for LG2 with 2-pole connector and clip flat male connector for neutral surface electrodes (art. no. 211 009) • non-autoclavable

Additional Accessories for LG2

Art. no.	Remote Control
262 001	Remote control Cable 2,5 m for LG2 with Redel connector grey 4-pole, including 4 keys to control the LG2 • non-autoclavable

262 003	**Termination connector**
	Connector to terminate RF channels during selftest

262300	**Trolley for LG2**
	incl. Silicone Device Base with 4 wheels, front wheels with brakes

262301	**Silicone Device Base for LG2**

262 302	**Transport case for LG2**
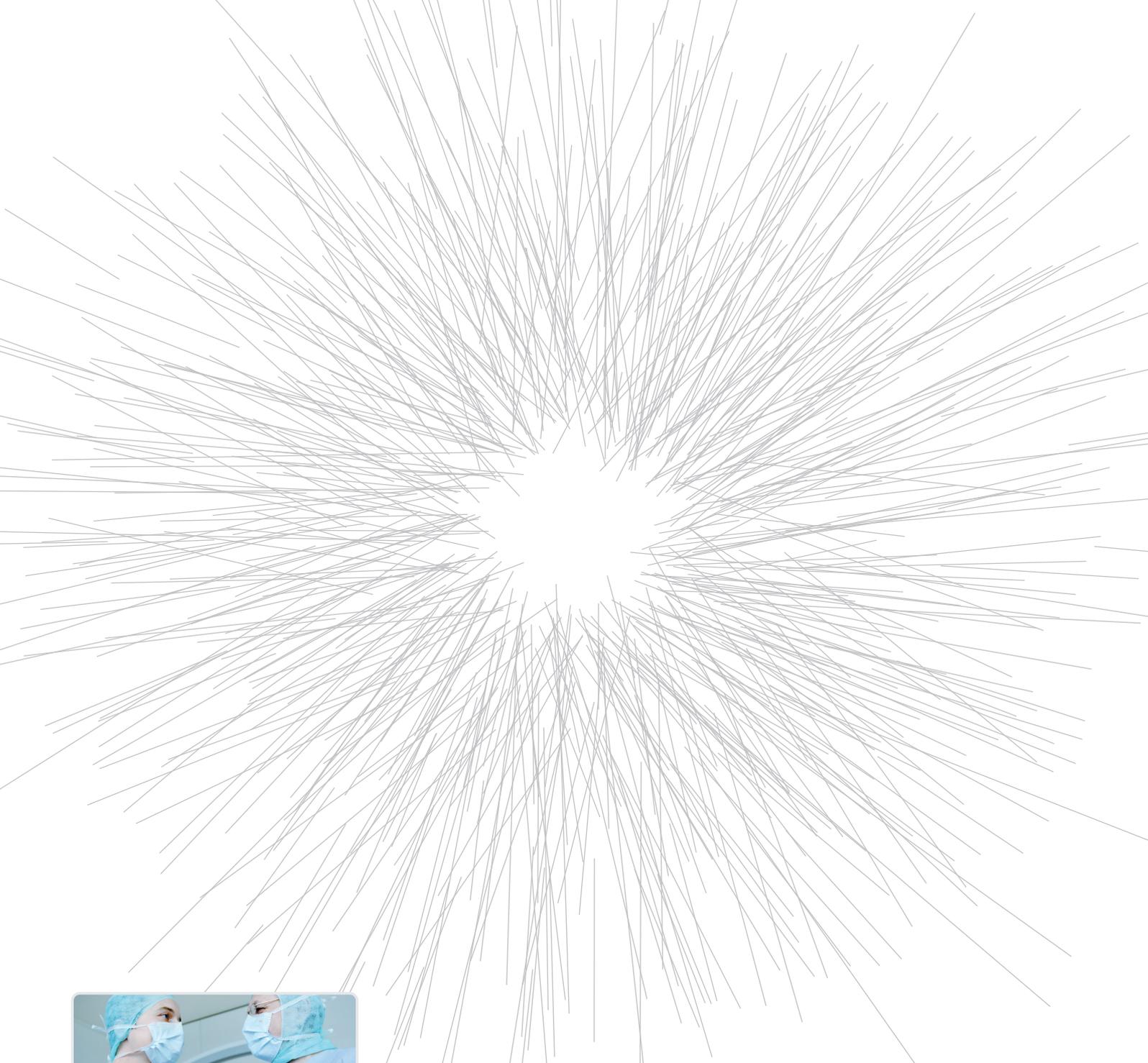
›› Partnership

›› Precision

›› Innovation

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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	170776256
Effective date	2021-05-25
Expiry date	2024-05-26
Frankfurt am Main	2021-05-25

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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411.20 Version 1.0

Annex to certificate
Certificate registration No.: 055435 MR2
Certificate unique ID: 170776256
Effective date: 2021-05-25

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	IIa/IIb
	Neurostimulator Systems	IIa
	Electrophysiologic Diagnostic Systems	IIa
	Cryo Systems	IIb
	Micro Electrode Recording Systems	IIa
	Lesion Generators	IIb
Disposable and reusable instruments and electrodes	Instruments and Electrodes for stimulation and recording	IIa/III
	Instruments and Electrodes for lesioning applications with accessories	IIa/IIb/III
	Biopsy Instruments	III
	Stereotactic Systems and accessories	Im/IIa
	Sterile cables and adapters	Is
Photoplethysmography sensors	Photoplethysmography sensors	IIa

KONFORMITÄTSERKLÄRUNG/ DECLARATION DE CONFORMITE/

DECLARATION OF CONFORMITY

Name und Adresse der Firma Nom et adresse de l'entreprise Name and address of the firm	**inomed Medizintechnik GmbH** **Im Hausgruen 29** **79312 Emmendingen, Allemagne/ Germany** **Tel.: +49 7641 9414-0, Fax: +49 7641 9414-94** **www.inomed.com**

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /
We declare under our sole responsibility that

das Medizinprodukt le dispositif médical the medical device	Instrumente, Elektroden und Zubehör für Läsionsanwendungen
	Instruments et électrodes pour lésions avec accessoires
(according to certificate registration no. 055435 MR2)	Instruments and Electrodes for lesioning applications with accessories
	Bezeichnung, Typ oder Modell siehe Anhang Nom, type ou modèle selon l'annexe Name, type or model see attachment
der Klasse / de la classe / of class	**IIa (Regel/règle/rule 6),**
	Nach Anhang IX der Richtlinie 93/42/EWG und der Änderungsrichtlinie 2007/47/EG selon l'annexe IX de la directive 93/42/CEE et la directive modificative 2007/47/CE / according to annex IX of direct. 93/42/EEC and as amended by directive 2007/47/EC

allen Anforderungen der Medizinprodukte Richtlinie 93/42/EWG vom 14. Juni 1993 und der Änderungsrichtlinie 2007/47/EG entspricht, die anwendbar sind / est conforme à toutes les exigences de la directive 93/42/CEE du 14 juin 1993 relative aux dispositifs médicaux et à sa directive modificative 2007/47/CE qui le concernent / meets all the provisions of the directive 93/42/EEC of 14 june 1993, as amended by directive 2007/47/EC which apply to it.

Konformitätsbewertungsverfahren/ Procédure d'évaluation de la conformité/ Conformity assessment procedure	Anhang/ Annexe/ Annex **II**, ohne Abschnitt / excluant la section /excluding Section 4
Konformitätsbewertungsstelle (falls beigezogen)/ Organisme resp. de l'évaluation de la conformité (si consulté)/ Notified Body (if consulted)	**DQS Medizinprodukte GmbH** August-Schanz-Str. 21, D - 60433 Frankfurt am Main, Germany

Emmendingen, 2021-05-25

Gültig bis/ Valide jusqu'au /Valid until: 2024-05-26   Saschka Busch / Quality Management

Ort, Datum / Lieu, date / Place, date	Name und Funktion / Nom et fonction / Name and function

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CE
0297

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Art. Nr / N° d'article / Art. No.	Produktbeschreibung / Désignation / Product description		Klasse / Classe / Class	GMDN
240100	Disposable cannula 22Gx50x4	isolated with mandrin	IIa	57972
240101	Disposable cannula 22Gx100x2	isolated with mandrin	IIa	57972
240102	Disposable cannula 22Gx100x5	isolated with mandrin	IIa	57972
240103	Disposable cannula 20Gx150x2	isolated with mandrin	IIa	57972
240104	Disposable cannula 20Gx150x5	isolated with mandrin	IIa	57972
240105	Disposable cannula 20Gx150x7	isolated with mandrin	IIa	57972
240106	Disposable cannula 22Gx100x10	isolated with mandrin	IIa	57972
240107	Disposable cannula 20Gx150x15	isolated with mandrin	IIa	57972
240108	Disposable cannula 20Gx150x10	isolated with mandrin	IIa	57972
240109	Disposable cannula 22Gx50x7	isolated with mandrin	IIa	57972
240110	Disposable cannula 20Gx100x5	isolated with mandrin	IIa	57972
240111	Disposable cannula 20Gx100x2	isolated with mandrin	IIa	57972
240112	Disposable cannula 20Gx100x10	isolated with mandrin	IIa	57972
240114	Disposable cannula 22Gx100x7	isolated with mandrin	IIa	57972
240120	Disposable cannula 17Gx100x2	isolated with mandrin	IIa	57972
240121	Disposable cannula 17Gx100x5	isolated with mandrin	IIa	57972
240122	Disposable cannula 17Gx100x7	isolated with mandrin	IIa	57972
240123	Disposable cannula 17Gx100x10	isolated with mandrin	IIa	57972
240125	Disposable cannula 17Gx150x5	isolated with mandrin	IIa	57972
240127	Disposable cannula 17Gx150x10	isolated with mandrin	IIa	57972
240140	Disposable cannula 18Gx115x2	isolated with mandrin	IIa	57972
240141	Disposable cannula 18Gx115x5	isolated with mandrin	IIa	57972
240142	Disposable cannula 18Gx115x7	isolated with mandrin	IIa	57972
240143	Disposable cannula 18Gx115x10	isolated with mandrin	IIa	57972
240152	Disposable cannula 22Gx100x5	isolated with mandrin	IIa	57972
240153	Disposable cannula 22Gx100x10	curved, isolated with mandrin	IIa	57972
240154	Disposable cannula 20Gx150x5	curved, isolated with mandrin	IIa	57972
240155	Disposable cannula 20Gx150x10	curved, isolated with mandrin	IIa	57972
240156	Disposable cannula 20Gx100x10	curved, sharp tip	IIa	57972
240157	Disposable cannula 20Gx100x10	curved, blunt tip	IIa	57972
240158	Disposable cannula 20Gx150x10	curved, sharp tip	IIa	57972
240159	Disposable cannula 20Gx150x10	curved, blunt tip	IIa	57972
240160	Insertion cannula	for TC cordotomy electrode	IIa	57972

Nr. 5.2. (marks row 240101)

Nr. 4.2. (marks row 240103)