# EC Design Examination Certificate

## Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

## Dr. Langer Medical GmbH

Am Bruckwald 26
79183 Waldkirch
Germany

that the design of the following device(s)

**Mono and bipolar disposable stimulation probes**

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 525502 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** Einmal-Stimulationssonden dated 2021-02-26

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

**Examination report:** 0_BerichtDr.Langer,AESondenZNS,Kl.III,210226c(V2).docx dated 2021-03-01

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

| | |
|---|---|
| Certificate registration no. | 525502 MRA |
| Certificate unique ID | 170774576 |
| Effective date | 2021-03-01 |
| Expiry date | 2024-05-26 |
| Frankfurt am Main | 2021-03-01 |

**DQS Medizinprodukte GmbH**

[redacted]

Sigrid Uhlemann
Managing Director

[redacted]

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.**

# EC-CERTIFICATE

**(Full quality assurance system)**

This is to certify that the company

## Dr. Langer Medical GmbH

Am Bruckwald 26
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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:

Devices and systems for electrophysiologic recording and stimulation; disposable and reusable electrodes and probes for recording or stimulation 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.

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|---|---|
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**DQS Medizinprodukte GmbH**

[redacted]

[redacted]

Head of Certification Body

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411.20 Version 1.0

## Annex to certificate
## Certificate registration No.: 525502 MR2
## Certificate unique ID: 170774577
## Effective date: 2021-03-01

# Dr. Langer Medical GmbH

Am Bruckwald 26
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| Device family | Device | Class |
|---|---|---|
| **Probes and Electrodes** | Disposable stimulation probes | IIa, III |
| | Saxophone electrodes | IIa |
| | Monopolar and bipolar needle electrodes | IIa |
| | Adhesive tube electrode | IIa |
| **Devices and systems** | Neuromonitor AVALANCHE | IIa |
| | Neuromonitor AVALANCHE PLUS | IIa |
| | Twister MM | IIa |

**DQS Medizinprodukte GmbH** | August-Schanz-Str. 21 | 60433 Frankfurt am Main

# Dr. Langer Medical GmbH

Am Bruckwald 26
79183 Waldkirch
Germany

**2024-06-20**

**Notified Body Confirmation Letter**

**Reference: 170774577 (NB 0297) & 170774576 (NB 0297)**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical device**

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

# Dr. Langer Medical GmbH

Am Bruckwald 26
79183 Waldkirch
Germany

SRN: DE-MF-000005524

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the

responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

**Schiwa Karimi**

[redacted]

Regulatory Affairs Manager

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name and Basic UDI-DI (as proposed by the manufacturer within the application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Einmal-Stimulationssonden / Disposable Stimulation Probes**<br>**~~04251807299029~~**<br>**4251807299029X** | Class III | N/A | 170774577 (NB 0297)<br>170774576 (NB 0297) |
| **Saxophonelektrode® / Saxophone electrode**<br>**~~04251807299098~~**<br>**425180729909AD** | Class IIa | N/A | 170774577 (NB 0297) |

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name and Basic UDI-DI (as proposed by the manufacturer within the application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **N/A** | N/A | N/A | N/A |

**Confirmation Letter Revision History**

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| ~~06.05.2024~~<br>Rev. 20.06.2024 | Cert-ID: 170774577 & 170774576 | Initial issue |