



# EU-Quality Management Certificate



This is to certify that the company

## Innovations Medical GmbH

Badstraße 11  
78532 Tuttlingen  
Germany

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

### Annex IX of the Regulation (EU) 2017/745

**CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION**

regarding the medical devices listed in the Annex:

The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.

The CE marking with the identification number of the Notified Body (0297) may be affixed on the devices listed on the certificate.

In case of devices placed on the market in sterile condition, devices with a measuring function or for devices which are reusable surgical instruments, the involvement of the Notified Body in these procedures shall be limited: in case of products that are placed on the market in sterile condition, limited to the aspects of manufacture concerned with securing and maintaining sterile condition; in the case of devices with a measuring function limited to the aspects related to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, as well as the related instructions for use.

|                              |                 |
|------------------------------|-----------------|
| Certificate registration no. | DE-MF-000005514 |
| Certificate ID               | 170779604       |
| Previous certificate-ID      | 170776455       |
| Effective date               | 2022-03-24      |
| Expiry date                  | 2027-01-06      |
| Frankfurt am Main,           | 2022-03-24      |



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zls.de  
BS-MDR-094

## DQS Medizinprodukte GmbH

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**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.**



**Annex to EU Quality Management Certificate**  
**Certificate registration No.: DE-MF-000005514**  
**Certificate ID: 170779604**  
**Effective date: 2022-03-24**



## **Innovations Medical GmbH**

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| Product name  | Risk class | Intended Use   |
|---|------------|--|
| Internal fixation systems of the upper and lower extremities incl. clavicle (implant plates and screws) | IIb        | The implants are used for temporary restoration for osteosynthesis |

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):  
516168\_A208710MED\_bericht\_S2\_b.docx dated 2021-11-29

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:  
n/a