



# Certificate

No. Q8 093054 0004 Rev. 00

**Holder of Certificate:**



**FLEIMA-PLASTIC GmbH**

Neustadt 2  
69483 Wald-Michelbach  
GERMANY

**Facility(ies):**

**FLEIMA-PLASTIC GmbH**

Neustadt 2, 69483 Wald-Michelbach, GERMANY

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:**

**The Provision of Design and Development Services, Tooling, Production and Assembling of Injection Molding Components for Medical Devices**

**Applied Standard(s):**

ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q8\\_093054\\_0004\\_Rev\\_00](http://www.tuvsud.com/ps-cert?q=cert:Q8_093054_0004_Rev_00)

**Report No.:** 713332049

**Valid from:** 2024-10-11

**Valid until:** 2027-10-10

**Date,** 2024-07-30



Christoph Dicks  
Head of Certification/Notified Body