



## EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A  
(Class IIa Devices)

**No. G20 040454 0018 Rev. 00**

### Manufacturer:

**SHERA Werkstoff-Technologie  
GmbH & Co. KG**

Espohlstraße 53  
49448 Lemförde  
GERMANY

SRN Manufacturer - DE-MF-000007202

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G20\\_040454\\_0018 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G20_040454_0018_Rev.00)

**Report No.:** 713266527

**Valid from:** 2023-06-23

**Valid until:** 2028-06-22

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2023-06-23



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 BS-MDR-099



Product Service

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**No. G20 040454 0018 Rev. 00**

**Classification:** Class IIa  
**Device Group:** Q010601 - DENTAL ALLOYS

**The validity of this certificate depends on conditions and/or is limited to the following:** ./.

### Revision History:

Rev.	Dated	Report	Description
00	2023-06-23	713266527	Initial issuance