



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. 01

Manufacturer: **SHERA Werkstoff-Technologie GmbH**

Espohlstraße 53
49448 Lemförde
GERMANY

SRN Manufacturer - DE-MF-000039599

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_01

Report No.:	713318278
Preceding Certificate No.:	G20 040454 0018 Rev. 00
Valid from:	2024-02-22
Valid until:	2028-06-22
Date of Initial Issuance:	2023-06-23

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Christoph Dicks
Head of Certification/Notified
Body



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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 (Class IIa Devices)

No. G20 040454 0018 Rev. 01

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	
01	2024-02-22	713318278	Amended: Change of certificate holder	Editorial change of certificate holder