



Certificate

No. Q7 021195 0059 Rev. 03

Holder of Certificate: **FREI medical GmbH**

Am Fischerrain 8
79199 Kirchzarten
GERMANY

Facility(ies):

FREI medical GmbH

Am Fischerrain 8, 79199 Kirchzarten, GERMANY

Production and Sales of medical training devices

Frei medical GmbH

Gerwigstr. 1, 79199 Kirchzarten, GERMANY

Production of medical training devices

Certification Mark:



Scope of Certificate: **Production and Sales of
medical training 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 (excluding subclauses 7.3, 7.5.1 and 7.5.6), 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:Q7 021195 0059 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q7_021195_0059_Rev.03)

Report No.: 713318524

Valid from: 2024-04-05

Valid until: 2027-04-04

Date, 2024-03-20



Christoph Dicks
Head of Certification/Notified Body