



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Product Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex VI
(Devices in Class I with measuring function)

No. G3M 021195 0058 Rev. 01

Manufacturer: **FREI medical GmbH**

Am Fischerrain 8
79199 Kirchzarten
GERMANY

Facility(ies):

FREI medical GmbH
Am Fischerrain 8, 79199 Kirchzarten, GERMANY

Product

Category(ies):

**Medical equipment for training with
measuring function**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for final inspection and testing of the respective devices / device categories in accordance with MDD Annex VI. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report no.: 713179320

Valid from: 2020-03-17

Valid until: 2023-03-19

Date, 2020-03-17

Christoph Dicks
Head of Certification/Notified Body

TUV SUD
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