



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



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in Class IIa, IIb or III)

No. G2 026237 0027 Rev. 00

Manufacturer:

Tzora Active Systems Ltd.

9980300 Kibbutz Tzora
ISRAEL

Product

Category(ies):

Active rehabilitation devices

**Exerciser / Training aid for disabled person
Class IIa**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. 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:G2 026237 0027 Rev. 00

Report No.:

713202064

Valid from:

2021-02-16

Valid until:

2024-05-26

Date,

2021-02-16

Christoph Dicks

Head of Certification/Notified Body