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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 0025 Rev. 00

Manufacturer: Tzora Active Systems Ltd.
9980300 Kibbutz Tzora
ISRAEL

Facility(ies): Tzora Active Systems Ltd.
9980300 Kibbutz Tzora, ISRAEL

Tzora Active Systems Ltd.
Industrial Zone Hartuv, HaMelacha St. 5, Hartuv, 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. See also notes overleaf.

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Date, 2019-04-17

Stefan Preiß

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