Simtat Levanon 38
Givat Koach 7318000, Israel
Tel. 972-3-5502020
Web site: www.tzora.com

MANUFACTURER'S DECLARATION OF CONFORMITY

We, the undersigned,

TZORA ACTIVE SYSTEMS LTD.

Simtat Levanon 38, Givat Koach 7318000, Israel

Declare that the following products:

Active Passive Trainer Models:

APT-1, APT-1+/APT-1 Plus, APT-1+ Double/APT-1 Plus Double

– Cat. No. AS-xx-0-nnn

APT-5, APT-5+/APT-5 Plus, APT-5+ Double/APT-5 Plus Double

– Cat. No. AS-xx-5-nnn

I-Motion **– Cat. No. AS-xx-7-nnn**

And the accessories for these products:

Footrests, High Supports for Footrest, Straight Hand Grips, Angled Hand Grips, Hemi Glove, Remote Control, Seat Assembly

UMDNS code: 15220

And the accompanying accessories are classified as Class IIa devices (MDD 93/42/EEC Annex IX rule 9) and have been designed and manufactured in accordance with the specifications of the following:

DIRECTIVE: Medical Devices 93/42/EEC (Annex V)

DIRECTIVE: 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)

Moshe Rosenberg
QA Manager
Tzora Active Systems

Date signed: 2021-05-05

CE 0123

Notified Body

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Expiry date: 31 Dec 2028

TZORA
Active Systems Ltd

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Table of Changes After 2021-05-26

Date	Description	Significant Change per MDR Art. 120(3)
2022-01-30	Addition of cat. nos. in device description	No
2024-03-03	1. Change in address 2. Addition of models for APT-1 and APT-5 3. Change in expiry date, conform changes in MDR Art. 120, following (EU) 2023/607	No No No
2024-07-30	Change in APT sub-models' product names: 1. APT-1 K to APT-1+ (or: APT-1 Plus) 2. APT-5 K to APT-5+ (or: APT-5 Plus)	No No No