theraplay
Cycles For Life

THERAPLAY LIMITED
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EU DIRECTIVE 93/42/EEC

Theraplay Ltd hereby declares that the following products are registered Class 1 devices, as notified with Medical Devices Agency, London UK and conform to the above legislation.

TX1 - TMX Tricycle
TT1 - Tracker Tricycle
TI1 - IMP Tricycle
TR1 - Terrier Tricycle
And all accessories

Theraplay also hereby states that manufacture of its products, as listed above, meet or exceed the following legislation:

NS-EN 12182: Technical Aids for Disabled Persons

NS-EN ISO 14971: Medical Devices - application of risk management to medical devices.

Theraplay also wishes to state that with regard to product design verification, a safe design of the above listed products had been established for several years prior to EU Directive 93/42/EEC and as such this information is sufficient to cover this requirement.

The same guidance notes issued to manufacturers also state that if a safe design has been sold on the market for a number of years and that the product has been performing as intended, which the above listed products have been, then this is also sufficient information to cover risk analysis requirements.

Internal risk analysis procedures are operated by Theraplay including post-production information procedures to detect any previously unknown hazards/risks during product use.

Signed on behalf of THERAPLAY LTD:

Position: Company Director

Name: Graeme R Macdonald

Dated: 10th November 2020