ERGOFIT
Qualität in Bewegung.

EC Declaration of conformity

This is to certify that the products

CYCLE 400

CYCLE 450

fulfil the requirements laid down in the following guidelines and standards.

- **2014/30/EU**
  EMC (electromagnetic compatibility) Directive
- **2014/35/EU**
  Low voltage directive
- **2015/863/EU**
  EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- **DIN EN 60335-1:2020**
  Household and similar electrical appliances - Safety – Part 1: General requirements

This declaration is valid for all products delivered from 02.05.2021 until 26.05.2024 and has been issued with full responsibility to the producer

ERGO-FIT GmbH & Co. KG
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Name of the CE document commissioner: **Alexander Harrer**
Address of the CE document commissioner: **siehe Anschrift Hersteller**

by:

Pirmasens, 02.05.2021

Managing director, Michael Resch

ERGOFIT
Qualität in Bewegung.

EC Declaration of conformity

This is to certify that the products

CYCLE 407 MED

CYCLE 457 MED

fulfil the requirements laid down in the following guidelines and standards.

- **93/42/EEC, class of models IIa, annex V**
  - DIN EN 60601-1:2013-12
    Medical electrical equipment – Part 1: General requirements for safety and essential performance
  - DIN EN 60601-1-2: 2022-01
    Medical electrical equipment – Part 1: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
  - DIN EN 60601-1-6:2021-11
    Medical electrical equipment – Part 1: General requirements for safety and essential performance – Collateral standard: Usability
  - DIN EN 62304:2016-10
    Medical device software - Software life-cycle processes
  - DIN EN 62366-1:2021-08
    Medical devices - Part 1: Application of usability engineering to medical devices
  - ISO 10993-1:2018-08
    Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- **DIN VDE 0750-238**
  Medical electrical equipment – Part 238 Particular requirements for the safety of crank ergometers

- **2015/863/EU**
  EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic Equipment (RoHS)

Notified body: (93/42/EWG only)
DQS Medizinprodukte GmbH
August-Schanz-Straße 21
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Identification number: 0297

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Address of the document commissioner: **see manufacturer´s address**

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