ERGOFIT
Qualität in Bewegung.

EC Declaration of conformity

This is to certify that the products

4000 CIRCLE Serie

4000 CYCLE Serie

4000 CROSS Serie

4000 RECUMBENT Serie

4000 STAIR Serie

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 02.05.2021until 26.05.2024 and has been issued with full responsibility to the producer

ERGOFIT GmbH
Blocksbergstraße 165
66955 Pirmasens
Germany

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

by:

Pirmasens, 19.01.2022

Managing director, Prof. Dr. Holger Krakowski-Roosen

ERGOFIT
Qualität in Bewegung.

EC Declaration of conformity

This ist to certify that the products

4000 TRAC Serie

4000 MIX Serie

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

- **2006/42/EG**
  Machinery directive
- **DIN EN 60335-1:2020**
  Household and similar electrical appliances - Safety – Part 1: General requirements
- **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)

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This is to certify that the products

4000 CROSS (X) MED Serie

4007 CROSS (X) MED Serie

4000 STAIR (X) MED Serie

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

- **93/42/EEC, class 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 2: 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 6: 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
- **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
60433 Frankfurt am Main
Identification number: 0297

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66955 Pirmasens
Germany

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

by:

Pirmasens, 19.01.2022

Managing director, Prof. Dr. Holger Krakowski-Roosen

ERGOFIT
Qualität in Bewegung.

EC Declaration of conformity

This is to certify that the products

4000 CYCLE MED Serie

4000 RECUMBENT (X) MED Serie

4000 CIRCLE (X) MED Serie

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

- **93/42/EEC, class 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 2: 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 6: 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)
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ERGOFIT
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This is to certify that the products

4000 TRAC (X) MED Serie

4000 MIX (X) MED Serie

4400 CYCLE X MED Serie

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

- **93/42/EEC, class 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 2: Electromagnetic compatibility - Requirements and tests
  - DIN EN 60601-1-6:2021-11
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