

Declaration of conformity

Manufacturer information

Manufacturer name: SilverFit B.V.
Address: Edisonweg 7, 3442 AC, Woerden, The Netherlands
Single Registration Number (SRN): NL-MF-000006613

Device information

Basic UDI: 87208922967REPHAGIAQE
Name: SilverFit Rephagia
Trade name: **SilverFit Rephagia**
CIBG Reg. number NL-CA002-2016-38993
EMDN Code Z12069092: Various physiotherapy and rehabilitation instruments – Medical device software.
Catalog number: RE
Intended purpose: SilverFit Rephagia is a software that provides motivational visualisations (games) for swallowing exercises.

Classification information information

Certification Class I Rule 13 (Annex VIII of Regulation (EU) 2017/745)
Conformity assessment route Annex II and III Technical Documentation
Declaration of conformity (Annex IV)
CE marking (Annex V)

This declaration of conformity is issued under the sole responsibility of SilverFit B.V.

The device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.
This declaration is supported by the Quality System approval to ISO 13485 issued by LRQA.

This declaration is valid until March 5th 2029



Signature: Joris Wiersinga - CEO

Woerden,
5 march 2024

Place and date of issue: