

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: 872089229673DBB
Name: SilverFit Time-of-Flight camera suite
Trade name: **SilverFit 3D**
CIBG Reg. number NL-CA001-2010-2992021
EMDN Code Z12069092: Various physiotherapy and rehabilitation instruments – Medical device software.
Catalog number: SF
Intended purpose: SilverFit 3D is a software that provides motivational visualizations (games) for training gross motor skills.

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: