

EC Declaration of Conformity

Manufacturer

Assistive Innovations BV

Single Registration Number NL-MF-000030625; Chamber of Commerce 09068063

Aalsbergen 7

6942 SE DIDAM

The Netherlands

This EU Declaration of Conformity is issued under the sole responsibility of Assistive Innovations BV.

Medical Device

iFLOAT FAMILY

with basic UDI-DI: 87208921040iFLOATNW

The iFLOAT FAMILY has the intended purpose to support the arm of the user and give assistance with arm movements by compensating against the gravitational pull.

Classification

Medical Device Class 1

Classification based on rule 1 of annex VIII of Regulation (EU) 2017/745.

Common specifications and standards applied.

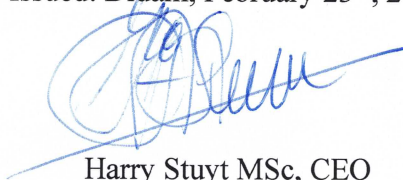
According to the manual issued by the manufacturer.

Conformity Assessment

Conformity assessment procedure: Appendix IX of the Regulation (EU) 2017/745.

The Medical Device referenced above is in conformity of the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 on Medical Devices.

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Harry Stuyt MSc, CEO