

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

iEAT FAMILY

with basic UDI-DI: 87208921040iEAT54

The *i*EAT FAMILY has the intended purpose to aid users, who are physically impaired in one or both of the upper extremities, with eating.

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.

Issued: Didam, March 27th, 2022

Harry Stuyt MSc, CEO