EU DECLARATION OF CONFORMITY

Manufacturer: Grasp AS

Address: Øyro 55, 5200 Os, Norway

Product Description: TABGIBLE SELF-LOGGING DEVICE

Type: PATIENT SYMPTOM RECORDER

Model(s): GRASP

Basic UDI-DI(s):

- 7073375GRASP00135
- 7073375GRASP00237
- 7073375GRASP00339
- 7073375GRASP0043B
- 7073375GRASP0053D
- 7073375GRASP0063F
- 7073375GRASP0073H

Classification: Class I according to Rule 13 (Annex VIII of MDR 2017/745).

Conformity assessment route:

- EC conformity declaration according to Art. 52(7) & Annex IV of Regulation (EU) 2017/745 (MDR)
- EC conformity declaration according to Annex III of Radio Equipment Directive (RED) 2014/53/EU

Applied standards for the RED Directive:

- ETSI EN 301 479-3 V2.1.1,
- ETSI EN 301 489-1 V2.2.3,
- ETSI EN 301 489-17 V3.2.4,
- EN 300 328 V2.2.2.

We, the Manufacturer, hereby declare that the above-mentioned device complies with the relevant provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and other relevant requirements of the RED 2014/53/EU and their relevant transpositions into national laws of the Member States in which the above-mentioned medical devices are distributed**.**

31-Oct-2023	Os, Norway	Ingvald Grindheim
Date of Issue	Place of Issue	Ingvald Grindheim, CEO Grasp AS