Public declaration regarding the manufacture and use of in-house devices by health institutions

Name of health institution: DeepPsy AG

Address: Forchstrasse 154, 8125 Zollikerberg, Zurich, Switzerland

DeepPsy AG declares that the devices described in the accompanying list are only manufactured and used within DeepPsy AG and to meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU 2017/745). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Date and location: 09.05.2024, Zurich

Name, function and signature of responsible person(s)

Mateo de Bardeci - CEO

LIST OF IN-HOUSE DEVICES

1. DEEPPSY BIOMARKERS SOFTWARE

- **Device identification (e.g. name, description, reference number):**
  DeepPsy Biomarkers

- **Device type (IVD/MD):**
  MD

- **Risk class of the device**
  Class IIa

- **Intended purpose:**
  DeepPSY Biomarkers is a in-house standalone software that assists in displaying, analyzing, and providing information through the examination of electrophysiological signals derived from human electroencephalogram (EEG) and electrocardiogram (ECG) data. The software is exclusively intended for use within DeepPsy AG and by specialists accredited by DeepPSY AG. The information provided by the software is intended to be used by physicians, who have to exercise their professional judgment when using this information.

- **Applicable GSPR fully met? (Y/N):**
  Yes

- **Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR):**
  Not Applicable