

FCC Statements

- Part 15.19 statement

This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.

- Part 15.21 statement

Change or Modifications that are not expressly approved by the manufacturer could void the user's authority to operate the equipment

- Part 15.105 statement

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Warnings

Do not use any component of the Byteflies Kit before reading these warnings and the IFU:

- Do not use the Byteflies Kit if any component is damaged.
- The Byteflies Kit is provided non-sterile.
- Please verify the LED status indicators to avoid misuse.
- If a trained operator or user experiences any adverse events while using the Byteflies Kit, discontinue the use and contact us immediately.
- Skin adhesives (either provided by Byteflies as an accessory or from a compatible third party provider) should be replaced if they no longer stick firmly to the skin or as indicated in their respective manuals.
- Similar devices may cause signal interference during data transmission. Avoid operating the Byteflies Kit near interfering devices.
- Keep the Byteflies Kit away from children and pets. The Sensor Dot and accessories may present a choking hazard. Never place or let anyone place a component of the device in their mouth.
- If any component of the Byteflies Kit fails to operate after attempting all suggested troubleshooting steps, contact support as soon as possible.
- Some Byteflies Kit components contain a battery which may present a risk of fire, explosion, or chemical burn if mistreated. Do not expose the Byteflies Kit to excessive heat or fire. Do not crush, puncture, or incinerate as doing so can result in fire, explosion, or the release of toxic gasses. Do not use or charge any component of the Byteflies Kit if it appears to be leaking, discolored, deformed, or in any way abnormal.
- All components of the Byteflies Kit should be returned to the healthcare provider or study staff at the conclusion of the prescribed period of use.

Troubleshooting

We're here for you!

Learn about new features and get help when you need it:

Website: <https://www.byteflies.com>

Online IFU: <https://www.byteflies.com/ifu>

Email support: support@byteflies.com

Phone support: +32 (0)3 294 74 99

EU office:

Borsbeeksebrug 22, 6th floor
2600 Antwerp
Belgium

US office:

530 7th Avenue- Suite 902
New York, NY 10018
USA

- If a LED on any component of the Byteflies Kit is red, refer to the troubleshooting steps in the online IFU (www.byteflies.com/ifu). If the issue persists, contact Byteflies.
- The Byteflies Kit is not a toy. Usage on children 3 years of age and older should be under strict supervision of an adult.
- Do not alter any component of the Byteflies Kit. Any modification is strictly prohibited.
- Consult the meaning of the LED colors in the online IFU to avoid misuse.
- If a trained operator or user experiences any adverse events while using the Byteflies Kit, discontinue the use of the device and contact us.
- To restart the Byteflies Kit, unplug it from power and plug it back in.
- Do not use in environments subjected to pressure lower than 700 hPa or greater than 1080 hPa.
- Do not use a power adapter or charging cable other than the one supplied with the Byteflies Kit.

Instructions for Use (IFU)

 **Byteflies Kit**
Legal Information

 Byteflies

Declaration of Conformity

The Byteflies Kit (Model 1) conforms to the essential requirements and provisions of the REGULATION (EU) 2017/745 on medical devices (MDR).

Manufacturer



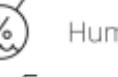
Byteflies NV

Borsbeeksebrug 22, 6th floor
2600 Antwerp
Belgium

Definition of Symbols



Manufacturer



Date of manufacture



Catalog number



Serial number



FCC marking



WEEE compliance



Consult the IFU



Type BF equipment
(IEC 60601-1)



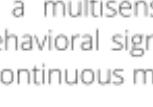
Class II insulation



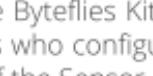
Prescription use only



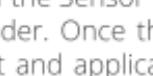
Medical device



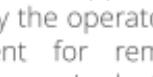
Temperature range



Humidity range



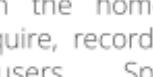
Pressure range



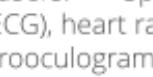
Ingress Protection code



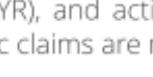
Includes RF transmitter



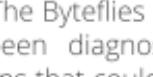
Keep out of direct sunlight



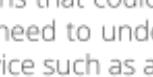
Keep dry



Choking hazard



MR unsafe



Unique device identifier

Intended Use

Safety Information

The Byteflies Kit is a multisensor device intended to collect non-invasive physiological and behavioral signals to be used in the clinic and/or home for subjects who need continuous monitoring.

Intended users: The Byteflies Kit and its accessories are intended to be used by trained operators who configure it in a medical environment (e.g. hospital). Users are wearers of the Sensor Dot, not operators of the Byteflies Kit, and are 3 years of age or older. Once the correct set up is configured, the user can take the Byteflies Kit and applicable accessories home to continue recording data as instructed by the operator. The user may be required to return to the medical environment for removal or reconfiguration of Byteflies Kit components and accessories by the operator.

- The Byteflies Kit cannot provide diagnoses. It only records physiological and behavioral signals as configured by and under the authority of the trained operator.
- The LED patterns only reflect battery status and operation mode. The LEDs do not reflect physiological status in any way and should never be interpreted as an indication of patient health.

Clinical indications: The Byteflies Kit and its accessories are intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, and transmit physiological and behavioral signals from users. Specifically, electroencephalogram (EEG), electrocardiogram (ECG), heart rate (HR), respiratory rate (RR), electromyogram (EMG), and/or electrooculogram (EOG) signals, with optional accelerometer (ACC), gyroscope (GYR), and activity index (AI) signals. It only acquires these signals; no diagnostic claims are made about the user's condition.

- Byteflies Kit components and accessories are only intended to be used by the user as instructed by the trained operator and the user cannot configure any component of the Byteflies Kit.
- The recorded data can only be used to assess heart, brain, muscle, or motion-related diseases when reviewed by a properly trained healthcare professional (e.g. cardiologist, pulmonologist, neurologist, physiologist).

Contraindications: The Byteflies Kit and its accessories should not be used on users that have been diagnosed with, or are suspected to have, life threatening conditions that could result in immediate danger. It should not be used on users that need to undergo an MRI scan or defibrillation, or have an active implanted device such as a pacemaker or defibrillator.

