

# FAQs

## Medical Device Regulations

### Do you have an Authorised Representative?

Yes, our Authorised Representative is Smartbox (EU) Assistive Technology Ltd. You will see this on the Declarations of Conformity and product labels.

Shaun McCormack is the Smartbox contact in the EU.

### Are Talk Pad and Touch Pad MDR compliant?

Yes they are MDR compliant.

Being consumer grade tablet computers, they apply EN 60950-1 - Information technology equipment, so we cannot apply the voluntary standard EN 60601-1 - Medical electrical equipment. However, we do extra testing to prove safety and performance, including EMC and leakage to Medical standards.

### Are EU Partners classed as Manufacturers?

No, Smartbox is the Manufacturer.

### Are EU Partners classed as importers?

Yes, you need make sure you meet [Article 13 - Obligations of importers](#).

### Where can I find the Declarations of Conformity?

Declarations of Conformity for Smartbox products are [available on our website](#).

### What is the UDI?

The Unique Device Identifier is the unique number used to register a device with the medical authority. You can find this number on the product label and on the Declaration of Conformity.

### Do you register devices with a notified body?

No, Class 1 medical devices do not require a notified body.

### Does adding Grid software to any device make it MDR compliant?

No - you need to meet the [requirements of MDR](#).

## Adding accessories

### If Partners add eye gaze accessories, alternative access methods, EC accessories, mounting systems or their own software, is the device MDR compliant?

According to MDR, if you change the conformity of the product (i.e. the tests required to prove safety and performance) or the intended use, user and environment of the product, then you have created a new product. You are now the manufacturer of that product and you must meet the requirements of MDR.

### If Smartbox add these accessories, is this MDR compliant?

In all cases a Grid Pad supplied by Smartbox with or without accessories is MDR compliant. Grid Pad is designed and tested as a modular system. We test with all accessories to assure safety and performance, and we ensure compliance with MDR.

## Compatible accessories

### Eye tracking camera brands:

- Alea Technologies
- Tobii Dynavox
- Iris Bond
- Eyetech
- Eyegaze Inc
- Seetech

### Alternative access methods:

- Switches (wired or Bluetooth)
- Nano Headmouse
- Quha Zono Mouse
- BJOY Wireless Ring
- Enpathia
- Integra Mouse Plus
- Emego
- Nous
- Cenomy Muscle Switch

### Environment Control accessories:

- GEWA
- BJOY
- Eldat Easywave
- Zwave

### Mounting systems:

- Rehadapt
- Daessy

For Daessy and Rehadapt, we have tested compatibility with the mounting interfaces only.

Because of the vast quantity of possible installation configurations it is up to the final installer to assure safety and performance of the mounting system.

This is best considered with the mounting system manufacturer and the wheelchair manufacturer as this is their area of expertise.

### Disclaimer:

If you have any doubts – please seek advice from compliance experts. We cannot offer legal advice.

