



Byteflies provides remote patient monitoring solutions consisting of wearable devices, cloud infrastructure, data analytics, and logistical services.

As a company working on every aspect of the virtual care value chain, having a common internal product and regulatory development language is very important. The V3 framework provides that language.

— **Benjamin Vandendriessche,**
CMO at Byteflies



The Problem

- » As an international solution provider, we must meet EU and U.S. FDA requirements for evidence for our medical devices that record biopotential and behavioral signals, and derive digital measures. Mapping medical device components onto the V3 Framework greatly assists with internal and external communication.



The Impact

- ✓ The V3 Framework gives us a common, unifying methodology for easier internal communication and collaboration.
- ✓ The V3 Framework allows us to optimize all components of Byteflies Care@Home products by rigorously evaluating the whole system. It supports our modular approach, allowing us to recombine different sensors and analytics fairly quickly, while maintaining compliance with international medical device standards.



The Resources

- » Byteflies Care@Home solutions exist of data collection, data processing, and data review components.
- » By maintaining a library of validated sensor and analytical components, we can optimize Care@Home solutions for dedicated patient populations and disease indications.
- » Each component of the Byteflies kit has individual evidentiary requirements that are similar but not identical.
- » Our team uses the DiMe [V3 Framework](#) to assign the V3 requirements to the individual components; helping us map out the technical file requirements for the different regulatory agencies in a more generic fashion for the development teams.