What is a medical device adhesive?

In short, one would think that a medical device adhesive is an adhesive used on any medical device. So what is a medical device? Loosely paraphrased from the FDA a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article….used to treat or diagnose.

Note that 93% of medical OEM suppliers serve transportation, electronics/IT and other major markets. Some of these suppliers segment medical off as only disposable devices that require biocompatibility testing.

More detailed background information about medical devices can be found here.

Biocompatibility and Medical Device Adhesives

Adhesives are considered components of medical devices. The FDA requires that the device meet specific biocompatibility which reflects the intended use of the device. They do not require that the individual components of the device carry specific testing or approval but often times the device manufacture prefers to use only components that meet the biocompatibility requirements.

As such adhesive manufacturers cure adhesive and test it similar to testing a sheet of plastic. The types of medical device adhesives commonly used to bond plastics include Cyanoacrylates and UV Curable adhesives. Most formulations will pass most of the majority of the biocompatibility testing – but if the particular adhesive that works best for your application hasn’t already been tested simply ask the manufacturer.

Epoxies are also considered medical device adhesives when used in various applications and although they don’t have as robust adhesion to some plastics they are often used as a locking mechanism. For example needles are bonded into hubs. The epoxy may have very little adhesion to the plastic hub – but the designs are such that by filling the well with adhesive, it locks the needle into the hub.

Adhesive Applications in which Biocompatibility Testing is Not Needed

Medical device adhesive applications involve so many more applications than only those on disposable medical devices which require biocompatibility. Using the FDA’s definition of medical device, consider that a “machine” has a motor, electronics, some lights, it’s assembled and put into a housing. Various types of adhesives are used in all of these applications which do not require specific biocompatibility testing. Two of these types are Structural Acrylic Adhesives and
Anaerobics. They are used extensively in medical equipment for bonding, sealing, threadlocking, retaining and gasketing.

In summary the term medical device adhesive is a marketing term that doesn’t necessarily indicate that the adhesive has had any biocompatibility testing. If specific biocompatibility testing is needed – ask the adhesive manufacturer for a test report or to have the testing performed.