The Importance of PRE-Coloured, Biocompatible and Pre-Tested ABS for Medical Device Approval

Biocompatibility is a key property that needs to be complied by most medical devices to fulfil with medical regulations (e.g. EU MDR or US FDA regulatory requirements). Final medical devices must be tested according to ISO 10993 and it is the responsibility of the Medical OEM manufacturer to make sure that such tests are conducted and passed. Biocompatibility tests are expensive and there is the risk that the required medical device may not pass one or more of them. The implementation of specific production procedures like GMPs (Good Manufacturing Practices), clean rooms etc. is critical, but positive test results cannot be assured without the correct pre-selection of all materials needed to produce each component of the device.

ABS plastics are widely used materials in external enclosures applications of medical devices. In this article we will discuss the different ABS material options available in the market to cover the biocompatibility needs of medical devices, and the risks associated with each one of them.

A first distinction is between what ABS manufacturers call as "medical ABS grade", "food contact grade", "healthcare grade" or "biocompatible grade". These definitions are very different and refer to different concepts. A medical grade includes a set of services and material properties that have been developed for medical device applications, but the term itself does not specify exactly what is really included or not. It is important to go through to the complete regulatory compliance list and to the set of services included, like for example the duration of the no-change agreement, notification periods, or the extended sample storage availability. Such services are specific to guarantee the long-term supply and quality support to the medical device industry and are normally not available for a general ABS portfolio. In any case, "medical ABS grade" does not automatically mean that the biocompatibility property was previously verified or even tested on the ABS as provided by the supplier. This should be indicated by the material manufacturer and even in this case it does not necessarily cover the PRE-coloured version of that biocompatible ABS, as it may refer only to the ABS in natural colour, without including the colour pigments. A food contact ABS refers to food or drug contact properties in terms of control of migration risks from the polymer to the food or drug during the device lifetime, but not to the set of services associated to the term "Medical ABS", nor specifically to the biocompatibility properties (IUPAC definition: ability of a material to be in contact with a living system without producing an adverse effect). Healthcare ABS grade is an even broader term than medical ABS grade and it may not be specifically indicated for medical devices. It may include for example cosmetic devices (e.g. body care enclosures, caps etc..) or devices used for general exercise, measurement and basic support (e.g exercise bike or mobility chairs that are not specifically for a disability) and does not necessarily require biocompatibility verified or pre-tested in the material.

The highest-risk option for a medical device is represented by selecting an ABS material that is not specifically declared biocompatible by the material manufacturer, and that is post-coloured during the injection moulding process with a colour masterbatch not declared biocompatible. The possibilities to pass the biocompatibility tests on a final device assembled with such material components are still existing, but very low.

The manufacturer denomination "biocompatible ABS grade" is therefore very important for medical device applications, but there are still several aspects and level of risks to be considered, also among the possible biocompatible ABS options available on the market.

A lower risk option is the choice of an ABS material that has been declared biocompatible by the ABS manufacturer based on raw material formulation, even if not on real biocompatibility tests conducted on the material. This type of solution can be combined with posterior ABS colouring with a colour masterbatch, that is also declared biocompatible by the masterbatch manufacturer, based on the formulation of the masterbatch (pigments + carrier material) and without performing real biocompatibility tests.

Luckily, safer alternatives than the ones previously mentioned for biocompatible ABS are also available. ABS material can be indeed pretested according to ISO 10993 by initiative of the material manufacturer, and the same can happen for the colour masterbatch through the masterbatch manufacturer. The level of safety increases if biocompatibility tests are repeated periodically, even if this represents higher costs for the material and masterbatch manufacturers.

Still, there is a biocompatible ABS version that offer higher levels of safety, and this is possible when the periodically repeated ISO 10993 tests are performed on the PRE-coloured ABS compound, including ABS and colour pigments. This normally doesn't happen in the case of POST-colouring natural ABS with a colour masterbatch during the injection moulding process. In fact, low volume annual needs and/or the many possible combinations of masterbatch-materials would not justify the high cost of the biocompatibility tests, not only in case of periodical tests repetition, but even in case of a single session of testing. On the other hand, if the colouring responsibilities are assumed by the ABS manufacturer, this higher value can be offered, increasing the level of biocompatibility safety for the interested medical device. In this case, in addition, not necessary variables that could provide further risks, like the masterbatch carrier, can be excluded. In fact, it is possible to consider the natural biocompatible ABS itself as carrier for the colour pigments, without needing any additional carrier. To understand this, we need to think about how a masterbatch is produced, creating a colour formulation made of a combination of different pigments. Such pigments are also in different concentrations, and compounded together through a material carrier, that acts as matrix for them to be homogeneously mixed. For example, in the case of a certain target colour, several pigments are needed (e.g. even very different ones, like white or black, etc...). Each one corresponds to a different substance (typically in powder form) with a different CAS number and a different own colour appearance. The sum of all the colour

contributions of the different pigments and the specific proportions in the formulation will give the specific colour appearance to the color masterbatch, and posteriorly to the post-coloured ABS material. A similar concept in terms of pigments management applies in the case of PRE-coloured ABS entirely produced by the ABS manufacturer, with the difference that it uses the natural biocompatible ABS as unique carrier of the colour pigments, avoiding the need of an additional carrier material from a third part. A specific integrated colour development department and a strict cooperation with a product stewardship department for regulatory support at the ABS manufacturer are key value-added resources to produce PRE-coloured ABS.

Pigments' regulatory compliance is required to be continuously supervised. If a colour formulation contains a pigment that cannot be used anymore due to regulatory updates, or in case of regulatory concentrations reduction, the target colour should be reviewed with an alternative pigment, and if necessary, a completely new colour formulation should be developed again. These are also the reasons why the periodical repetition of biocompatibility tests on PRE-coloured ABS are so important and offer additional safety and value.

PRE-coloured biocompatible ABS, periodically pretested, offers also additional advantages vs POST-coloured biocompatible ABS with masterbatch: the problem of masterbatch dosage during the injection moulding process is eliminated. This alone represents a relevant risk of exceeding the pigments concentration in the compound that may affect the biocompatibility tests results on the final device. Another possible side effect is the colour instability on the injected part during different production campaigns, or colour inconsistence of a same part produced at different moulders with the same or different masterbatches.

There are more advantages of PRE-coloured vs POST-coloured biocompatible ABS: the complete formulation ABS and colour pigments can be contained in a unique safe place (e.g. Drug Master File – DMF# at the FDA), that can be easily accessed by notifying bodies and regulatory authorities, making easier the PRE-coloured ABS medical application compliance and speeding up the medical device approval process. New pigments can be included in new colour formulations and tests can be repeated acc. to ISO 10993 along with the complete PRE-coloured ABS compound. Furthermore, these new colour formulations can be added to the already existing DMF through an amendment, updating all the information needed for the required verifications of the medical device approval authorities.

The biocompatibility of PRE-coloured ABS can be also assured in specific sustainable medical ABS versions that are ISCC+ certified with a mass balance approach. The first ABS manufacturer to obtain the ISCC+ certification has an important advantage in comparison to the others, because they already introduced certified sustainable feedstocks in their supply chain already several years ago. During all these years, biocompatibility tests on PRE-coloured medical ABS grades continue to be periodically performed with success and new sustainable versions with Certified Raw materials (CR) are being accepted at the FDA for the inclusion in the same DMF# of the biocompatible fossil version.

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