SCIENTIFIC REPORT

Medical device classification of dental surgical guides

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Various competitor products for the fabrication of dental surgical guides are classified as class I medical devices. And yet others as class IIa medical devices, as for example VOCO's V-Print SG. However, what exactly is the difference between these classifications and what does this mean for the user? Why do manufacturers like to upgrade their surgical guide material from MD I to MD IIa? Here are some explanations:

The DIN EN ISO 17664 regulates the sterilisation of dental surgical guides. This international standard defines the general requirements for the preparation of medical devices, including individually fabricated dental surgical guides. This standard applies for both single-use instruments that are sterilised before initial use, which would correspond to a dental surgical guide, as well as for the multi-use instruments. If instruments and accessories are supplied non-sterile, the manufacturer must at least specify a suitable sterilisation procedure so that the functional safety of the product is not affected. VOCO fulfils this specification with V-Print SG by enabling a sterilisation at 134°C for a maximum of 5 minutes. Some manufacturers do not fulfil this specification with their material!

The decision whether a products is classified as a medical device of class I or class IIa is not only dependent on the duration of the contact with the patient, but also on the intensity of the procedure. However, the sterilising capability arises exclusively from the clinical requirements of the treatment. Often the dental surgical guide is fixed only by contact with the hard tissue (tooth-supported) or soft tissue (mucosa-supported). In these cases, the material for the dental surgical guide is declared as a medical device of class I, since it is an invasive application. **However, as soon as the treatment requires a surgically invasive procedure for the usage of a surgical guide (e.g. bone-supported surgical guide), the classification as medical device of class IIa is required.**

The medical device directive 93/42/EWG regulates the classification of medical devices such as dental surgical guides. This classification is always based on the location of the contact (degree of invasiveness, i.e. invasive or non-invasive) and the duration of the contact with the patient in order to determine the class of the medical device. These classes reflect the risk associated with the product and its therapeutic use. The appropriate products are designed and manufactured to reduce this risk.

VOCO customers are equipped with a medical device of class IIa in compliance with the regulations and can use V-Print SG for any dental surgical guide without hesitation.