



TECHNICAL FILE

Object: “FLEXIBLE SPATULA ”

Manufacturer: Dental Market S.r.l.



Use destination: these products are used in some medical / aesthetic fields, during some different operation; they are used to mix the different preparations of each field, as plaster and alginates for the dental field, etc.

This products are made of:

- Shock-proof polystyrene

These products are reusable and they are supplied in a non sterile and in a multiple packaging.

Warning: These devices are placed on the market in a NON STERILE packaging; for this reason they have to be cleaned before use, according to the operator’s final use. They are supposed to be used with disposable gloves.

Classification: the product in not to be considered as medical device, according to the European Directive 93/42/CEE (and following supplementary modifications – ref.: European Directive 2007/47/CE), because it doesn’t meet to the definition provided from the article 1 as “medical device” , because it isn’t a product, that used itself or combined with something else, (..) is destined from the producer to be used on the human being, for diagnostic purpose, prevention, control, therapy or attenuation of a disease, of an injury or of a handicap; study, substitution or modification of the anatomy or of a physiological process; intervention on the conception.

Packaging: plastic bag

Way of conservation: far from direct heat