

Object: declaration of conformity of the medical device named "SEKUTIP – non sterile disposable tip for air/water syringe for dentistry use", produced in Dental Market srl, in conformity to the essential requirements of the I enclosed to the European Directive 93/42/CEE (and following modifications – ref.: European Directive 2007/47/CE) as wrote in the VII enclosed of the above-mentioned Directive.

With this document, **Dental Market srl**, in the person of the General Manager Luciano Grotti, producer of the medical device named "SEKUTIP – DISPOSABLE TIP FOR AIR/WATER SYRINGE" declare the following:

"the products described in the technical file "SEKUTIP – DISPOSABLE TIP FOR AIR/WATER SYRINGE"" satisfy all the essential requirements of the I enclosed of the European Directive 93/42/CEE and the following supplementary modifications. (ref.: European Directive 2007/47/CEE)".

The codification has the following structure: TD0760xxxxxxxx where: TD0760 identify the family "**disposable tip for air/water syringe**" and xxxxxxx is univocally string which identify the medical device by the colour.

For this purpose **Dental Market srl**, guarantee and declare the following:

- 1. the device in object satisfy the applicable dispositions of the European Directive 93/42/CEE (and following supplementary modifications ref.: European Directive 2007/47/CE).
- 2. the device in object belong to the I class, 5 rule of the enclosed IX of the European Directive 93/42/CEE (and following supplementary modifications ref.: European Directive 2007/47/CE).
- 3. the medical device in object is commercialised in a non sterile packaging
- 4. the manufacturer will save and will put all the documentation of the medical device at the Competent Authority disposition (technical file and registrations of the production) for a minimum period of 8 years from the last production.
- 5. the manufacturer notified to the competent authority, after the beginning of the business of the medical devices in object, the application of the procedure of post-selling surveillance of the products as required from the European Directive 93/42/CEE (and following supplementary modifications ref.: European Directive 2007/47/CE).

Luciano Grotti (Direzione Generale)

BOZZANO MASSAROSA, 09/12/2015