**<u>Object</u>:** **declaration of conformity of the medical device named "Surgical Instruments for dental 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 "SURGICAL INSTRUMENTS FOR DENTAL USE" declare the following:

*"the products described in the technical file "*SURGICAL INSTRUMENTS FOR DENTAL USE*" 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: TDWXXXYY
where: TD identify the medical devices manufactured by Dental Market, W (the numbers used are 4,5,8 and 1) identify the family of surgical instruments; XXX is a string of 3 numbers, which identify univocally the medical device; YY is an alphanumeric string (maximum of 2 numbers) which identify univocally the variation of the medical device.

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, 05 July 2016