Object: **declaration of conformity of the medical device named "flexible saliva ejectors for dental use", produced in Dental Market srl located in via Sarzanese 1252 55054 Massarosa (Lu) Italy, 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 V and 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 "flexible saliva ejectors for dental use" declare the following:

*"the products described in the technical file "*flexible saliva ejectors 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: **TD3400/XXXYZZZ orq\w**
TD3410/XXXYZZZ where:

- TD3400 identify the family of "Saliva ejectors 13 cm" and TD 3410 identify the family of "saliva ejectors 15 cm"
- X (maximum 3 letters), if it is presents, identify the colour of the saliva ejector (the absence of it identify the colour transparent)
- Y (maximum 1 number), if it is presents, identify the quantity of the saliva ejectors per bag
- Z (maximum 3 letters), if it is presents, identify the personalization of the bag of 100 pcs

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 IIa 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 KIWA CERMET ITALIA SPA VIA CADRIANO 23 - CADRIANO40057 GRANAROLO DELL'EMILIA- BO ITALY (technical file and registrations of the production) for a minimum period of 10 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, 20/12/2017