Object: **declaration of conformity of the medical device named "MASKS, REELS AND SELF SEAL PUOCHES", 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 "MASKS, REELS AND SELF SEAL PUOCHES" declare the following:

"the products described in the technical file "MASKS, REELS AND SELF SEAL PUOCHES" *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:
Masks: TD703x-TD703xA
where: TD703 identify the masks and X number identify the colour of the medical device (0 light blue, 1 green, 2 pink, 3 yellow, 4 lilac, 5 orange, 6 white) and A identify the bands which replace the elastics.
Reels for sterilization: TD950x
Where TD950 identify the sterilization flap reels, x identify the dimension.
Self seal pouches for sterilization: TD952x
Where TD952 identify the self seal pouches for sterilization, x identify the dimension.

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, 3 June 2020