Subject:: **declaration of conformity for medical device denominated "Aspirasaliva flessibile" (flexible saliva ejector), manufactured by NostrumS.r.l. in accordance with essential qualifications of the European Community Directive 93/42/CEE, see enclosed form I (and successive additional modification – ref. European Directive 2007/47/CE) as described in the enclosed forms V e VII of the** abovementioned **directive.**

Herewith the company Nostrum S.r.l. in the person of Luciano Grotti General Director, manufacture of the medical device denominated "ASPIRASALIVA FLESSIBILE (for dental use)", declares the following:

"the articles described in the technical brochure "ASPIRASALIVA FLESSIBILE (for dental use)"satisfy all the essential qualification requested by the enclosed form I of the European Directive 93/42/CEE and successive additional modification (rif.: European Directive 2007/47/CE)".

The general structure of the code is as follows:

3400/ xx/y/zzz - 3410/ xx/y/zzz

where: 3400 identifies the family of the "short saliva ejector "; identifies the family of the "long saliva ejectors"; xx strig of two numerical characters identifies the color (i.e. 01 trasparent; 02: opaque white; 03 opaque green; 04 trasparent blue; ecc.); y identifies the quantity in each packet (i.e.: 1=100pcs.; 2=250pcs.); zzz string of three alphanumeric characters identify an eventual personalization

To this effect the company Nostrum S.r.l. guaranties and declares the following:

1. the abovementioned device will satisfy the application of the European Directive instruction 93/42/CEE (and successive additional modification – ref European Directive 2007/47/CE).
2. the abovementioned device is to be considered appertaining to the class IIa, rule 5 of the enclosed IX European Directive93/42/CEE (and successive addition modification – ref.: European Directive 2007/47/CE)
3. the abovementioned device is marketed in non sterile packets
4. the manufacturer undertakes to conserve and make available from the notification body all relative documentation regarding the device (technical brochures and products registration) for a minimum period of 8 years from the data of the last production.
5. the manufacturer after marketing the abovementioned medical as notified the competent authority of the application of the after sales control procedure as required by the European Directive 93/42/CEE (and successive addition modification – ref.: European Directive2007/47/CE) .

Luciano Grotti
(Direzione Generale)

CAPEZZANO PIANORE, ……29/03/2019..