VANNINI DENTAL INDUSRTY SRL
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DECLARATION OF CONFORMITY

CE

As per annex VII of European Medical Devices Directive 93/42 EEC Directive as amended by 2007/47/EC Directive

The undersigned

VANNINI DENTAL INDUSTRY S.r.l. Via di Campigliano 55/A 50012 GRASSINA (FI) - ITALY

Declares

Under their own responsibility that the products "silicones and alginates for impression taking and relative catalyst and accessories":

055001 PRESTIGE PUTTY	056004 -056002 PROTESIL PUTTY
055002 PRESTIGE PUTTY SOFT	056006-056011 PROTESIL LIGHT
055101 PRESTIGE A PLUS PUTTY	056021 PROTESIL CATALYST GEL
055105 – 055205 PRESTIGE REGULAR	002020 CLIP ALGIN
055106 – 055206 PRESTIGE LIGHT	056017 PROTESIL MINI KIT
055108 – 055208 PRESTIGE A PLUS LIGHT	055107 PRESTIGE HYDROLIGHT
055028 PRESTIGE MINI KIT	002010 CROMATIC
055010 – 055210 PRESTIGE MONOPHASE	002000 KROMALGIN PIU'
055015 – 055215 PRESTIGE BITE CAD CAM	005011 PROTESIL CHROMATIC
055122-055123 PRESTIGE VDX 5:1 PUTTY SOFT	005006 PROTESIL NORMAL RIGID
055112-055113 PRESTIGE VDX 5:1	005002 PROTESIL ELASTIC RAPID
058021 PRESTIGE INTRA ORAL TIPS	055120 DYNAMIC MIXING TIPS
101024/101025 SUPERFORM TRAY SYSTEM	051030 PRESTIGE DISPENSER
058025-058026 PRESTIGE MIXING TIPS	058005 PRESTIGE UNIVERSAL ADHESIVE

(from now own referenced as "the products")

are conforms to all the applicable Requirements set forth Directive 93/42/ EEC as amended by 2007/47/EC Directive concerning medical devices (from now on referenced as "MDD").

- The products complies with the essential requirements listed in Annex I of the MDD.
- The products belongs to class I according to the classification Rules listed in Annex IX of the MDD.
- The products is sold in a NOT STERILE package;
- The products DOES NOT HAVE A MEASURING FUNCTION;
- The device in object is NOT MEANT TO BE USED FOR CLINICAL INVESTIGATIONS;

We have prepared the technical documentation described in Annex VII, section 3 of the MDD and we shall make such documentation available to the national authorities for a period ending at least 5 (five) years after the last products have been manufactured.

We shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions.

Applied technical specification: ISO 4823 and EN ISO 21563

VANNINI DENTAL INDUSTRY SRL

Jaime Sandoval
President

Date: 10/03/2015