VANNINI DENTAL INDUSRTY SRL
Via di Campigliano 55/A – 50012 Grassina – FI– ITALIA
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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”:

Product	Code
PRESTIGE PUTTY	055001
PRESTIGE PUTTY SOFT	055002
PRESTIGE A PLUS PUTTY	055101
PRESTIGE REGULAR	055105 – 055205 - 055405
PRESTIGE REGULAR FAST	055505 – 055605 - 055420
PRESTIGE LIGHT	055106 – 055206 - 055425
PRESTIGE A PLUS LIGHT	055108 – 055208 - 055408
PRESTIGE HYDROLIGHT	055107 - 055207 - 055407
PRESTIGE MINI KIT	055028
PRESTIGE MINI KIT SOFT	055029
PRESTIGE A PLUS MINI KIT	055030
PRESTIGE MONOPHASE	055010 – 055210 - 055410
PRESTIGE BITE CAD CAM	055015 – 055215 - 055415
PRESTIGE VDX 5:1 IMPLANT	055112-055113
PROTESIL PUTTY	056004 -056002
PROTESIL LIGHT	056011 - 056116 - 056006A
PROTESIL CATALYST GEL	056021
PROTESIL MINI KIT	056217 - 056017A
SUPERFORM TRAY SYSTEM	101024 - 101025
KROMALTROPIC	002030 - 002031
CLIP ALGIN	002020 - 002025
CROMATIC	002010 - 002015
KROMALGIN PIU’	002000 - 002003
PROTESIL CHROMATIC	005011
PROTESIL NORMAL RIGID	005006
PROTESIL ELASTIC RAPID	005002
PRESTIGE UNIVERSAL ADHESIVE	058005

(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;

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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: 10/01/2021