Ministero della Salute
DGDMF
0073050-P-15/10/2021
I.5.l.e.1/2021/1448
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Imposta di bollo assolta

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO 3

DGDMF/3/P/I.5.l.e.1/2021/1448

HAVING REGARD to the Legislative Decree n. 46/1997 and its following amendments;
HAVING REGARD to article 120 par. 3 of the EU Regulation 2017/745 related to transitional provisions on the free movement and placing on the market of medical devices marked CE pursuant to Directive 93/42/CEE;
HAVING REGARD to the request ref. 51957-A-19/07/2021 updated on October 14, 2021 submitted by the Company **Vannini Dental Industry S.r.l.** with registered office in Via di Campigliano, 55/A – 50012 Grassina (FI), Italy - VAT Nº 03651220489;
WHEREAS the Company paid the fees required by Ministerial Decree January 16, 2019;
HAVING REGARD to the official deeds:

IT IS ATTESTED

that, the Company **Vannini Dental Industry S.r.l.** with registered office in Via di Campigliano, 55/A – 50012 Grassina (FI), Italy, is the manufacturer and has marked CE as medical devices, according to the procedures provided by the Directive 93/42/CEE pursuant to art. 120 par. 3 of EU Regulation 2017/745, the following medical devices: **Prestige Putty** code: 055001 - **Prestige Putty Soft** code: 055002 - **Prestige A Plus Putty** code: 055101 - **Prestige Regular** codes: 055105 - **Prestige Light** codes: 055106, 055206, 055425 - **Prestige A Plus Light** codes: 055108, 055208, 055408 - **Prestige Hydrolight** codes: 055107, 055207, 055407 - **Prestige Monophase** codes: 055010, 055210, 055410 - **Prestige Bite CAD CAM** codes: 055015, 055215, 055415 - **Protesil Putty** codes: 056004, 056002 - **Protesil Light** codes: 056011 - **Protesil Catalyst Gel** code: 056021 - **Clip Algin** codes: 002020, 002025 - **Cromatic** codes: 002010, 002015 - **Kromalgin Più** codes: 002000, 002003 - **Protesil Chromatic** code: 005011 - **Protesil Normal Rigid** code: 005006 - **Protesil Elastic Rapid** code: 005002 - **Prestige Universal Adhesive** code: 058005.
The above mentioned products, according to the article 4 of Directive 93/42/CEE pursuant to article 120 par. 3 of Regulation 2017/745, can freely circulate and can be placed on the market in Italy and all over the European Union.
This document has been issued in an unique original version upon request of the manufacturer in order to export medical devices to **Countries outside European Union**.
It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.
It is only allowed to show or to delivery it, upon request of the customs or Health Competent Authorities of the importing country.

The Health Manager
Dott. Marco Musella
Marco Musella

DDP