



# EC DECLARATION OF CONFORMITY

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**Manufacturer:** HANDAE CHEMICAL CO.,LTD

**Address:** 56-28, Songdu 4-gil, Jincheon-eup,  
Jincheon-gun, Chungcheongbuk-do, Korea  
TEL : +82(31)704-0694 / FAX : +82(31)718-0008  
E-mail : hdc@handae.co.kr / www.handae.co.kr

**European representative:** OBELIS S.A  
Bd Général Wahis, 53, 1030 Brussels Belgium  
TEL: +32 2 732-59-54

**Product:** PERFECT-F VPS PUTTY, Dental impression material

**Classification:** Class I (Annex IX Rule 5)

**GMDN Code:** 35866, Impression material, dental, silicone

**Conformity Assessment Route:** Annex II excluding section 4 MDD 93/42/EEC as amended by 2007/47/EC

**Applied reference:** EN ISO 13485:2012, EN 980:2008, EN 14971:2012, ISO 4823:2015

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

2020. 06. 01

Signature

Jongwon Lee, CEO

LEE JONG WON

President on behalf of  
HANDAE CHEMICAL CO.,LTD