



# EC DECLARATION OF CONFORMITY

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

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**European representative:** OBELIS S.A  
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**Product:** PERFECT BITE, 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, DIN 13903:2017

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

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President on behalf of  
HANDAE CHEMICAL CO.,LTD