



# EC DECLARATION OF CONFORMITY

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

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**European representative:** OBELIS S.A  
Bd Général Wahis, 53, 1030 Brussels Belgium  
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**Product:** hanFIL flow, Light curing dental composite resins

**Classification:** Class IIa (ANNEX IX Rule5 )

**GMDN Code:** 35875, Dental material, filling/retorative, polymer based

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

**Notified Body:** SGS United Kingdom Ltd, Notified Body 0120  
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK

**Applied reference:** EN ISO 13485:2012, EN ISO 14971:2012, ISO 4049:2009, EN980:2008

**EC certificate:** KR13/02049

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

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President on behalf of  
HANDAE CHEMICAL CO.,LTD