



EC DECLARATION OF CONFORMITY

Manufacturer: HANDAE CHEMICAL CO.,LTD

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

Product: HanBase, Light Curing Cavity Liner

Classification: Class IIa (ANNEX IX Rule5)

GMDN Code: 16182, Cavity liner, calcium hydroxide

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

LEE JONG WON

**President on behalf of
HANDAE CHEMICAL CO.,LTD**