



EC DECLARATION OF CONFORMITY

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: HanCore, Dental filling materials

Classification: Class IIa (ANNEX IX Rule5)

GMDN Code: 38789, Dental material, core build-up

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