



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: HanTemp Crown

Classification: Class IIa (ANNEX IX Rule7)

UMDN Code: UMDNS-Code: 16-723

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 10477:2004, EN980:2008

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

LEE JONG WON

President on behalf of
HANDAE CHEMICAL CO.,LTD