

Declaration of Conformity

to the Medical Device Directive,
93/42/EEC as amended by 2007/47/EC



JOIN ENTERPRISE Co.,Ltd

45, Gyeonggidong-ro, Namsa-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Korea

Product Name: Optima cast

(OCF200,OCF300,OCF400,OCF500)

(OSF210,OSF312,OSF415,OSF430,OSF530,OSF545,OSF645)

(OSF200,OSF300,OSF400,OSF500)

Classification/Rule: Class 1, Rule 1

Conformity Assessment Route: Annex VII

Standards: (EN)ISO13485;2003, (EN)ISO14971:2007, ISO10993-1:2009

EN980:2008, EN1041:2008

We declares under our sole responsibility that the above products to which this declaration relates, and which bears the CE Marking, is(are) in conformity with the applicable requirements of EC Directive 93/42/EEC and the amendments of 93/42/EEC(2007/47/EC), concerning medical devices.

EC Representative : KTR Europe GmbH

- address : Mergenthalerallee 77, Eschborn, Hessen, 65760, Germany

- Tel : +49(0)6196-887170

2, July, 2020

President H C .JANG

Join Enterprise. Co., Ltd.

Join Enterprise Co., Ltd



Giám Đốc

Jang Kyounggho