

	Declaration of Conformity	Doc. No.	TCFS06-DOC-01
		Rev. No.	0
	Osstem Class I devices	Issued date	2021.01.22
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Manufacturer: OSSTEM IMPLANT Co., Ltd. (Osstem Busan Plant)
(66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Korea)

EU Representative: DEUTSCHE OSSTEM GmbH
(Mergenthalerallee 35-37, 65760 Eschborn, Germany)

declares that the subject products are falling within class I and in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC.

Conformity assessment procedure: 93/42/EEC Annex VII

- **Subject products (Type / Model)**

Impression Tool System
Surgical Instrument System
Template System
HiOssen Tools

Osstem Implant Co., Ltd is exclusively responsible for the declaration of conformity.



Date & Signature of authorized person

2021.01.22

Son Hee Kwon

Print name

Director of Regulatory Affair

Print title