Declaration of Conformity

CE 2195

according to the Medical Devices Directive 93/42/EEC

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directives 98/79/EC, 2000/70/EC and 2001/104/EC, Regulation (EC) No. 1882/2003 and 2007/47/EC

Manufacturer:	NEXOBIO Co., Ltd.
Address	601, Center B/D, 27, Sanseong-ro 92beon-gil, Sangdang-gu, Cheongju-si, Chungcheongbuk-do, Korea.
European Representative:	MEGA DIS DEPOSU
Address	Molla Gurani Mah, Sarayhamami, Sk. No:32/B Findikzade, Istanbul, Turkey
Product :	Treatment Materials for dental impression
Type Designation:	T stat
Classification :	Class Ⅰ by Rule 5 of Annex IX, Council Directive 93/42/EEC
GMDN Code:	N/A

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

EN 980 : 2008
EN ISO 13485 : 2016
EN ISO 14971:2012
EN 1041:2008
ISO 7405:2008
ISO 7491:2000
EN 15223-1:2012

This Declaration of Conformity is based on the EC Directives 93/42/EEC, ***Annex II (excluding section 4)*** *under the supervision of Notified body,* SZUTEST(2195)

Notified body: SZUTEST, Notified Body number 2195
Szutest Teknik Kontrol ve Belgelendirme Hizmetleri Ticaret Limited Şcozrketi (Notified Body No. : 2195) Yukarı Dudullu Mahallesi Nato Yolu Caddesi Çm Sokak No: 7 Üraniye/İTANBUL, Turkey

EC Certificate No.: 2195-MED-1328403

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Start of CE-marking: 2013.10

Place: Cheongju City **Date: July.22. 2020** **President Sung-Joon Choi**

Sung Joon Choi