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 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 :	Root Canal Filling Materials
Type Designation:	MTA Cem1.0, MTA Cem 0.14 . MTA Cem 0.3,MTA Cem LC
Classification :	Class IIa by Rule 7 of Annex IX, Council Directive 93/42/EEC
GMDN Code:	38778 (Dental material, filling, temporary)

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

EN 980 : 2008
ISO 10477 : 2004
EN ISO 13485 : 2016
EN ISO 14971:2012
EN 1041:2008
NBOG BPG 2010-1

EN ISO 10993-1:2009
EN ISO 10993-3:2009
EN ISO 10993-5:2009
EN ISO 10993-6:2009
EN ISO 10993-10:2010
EN ISO 10993-11:2009

ISO 7405:2008
ISO 7491:2000
EN ISO 15223-1:2012
EN 62366:2008
EN 1641:2009
MEDDEV 2.7.1 Rev.3
MEDDEV 2.12.1 Rev.8
MEDDEV 2.12.2 Rev.2

This Declaration of Conformity is based on the EC Directives 93/42/EEC, ***Annex V (production Quality Assurance System)*** *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

Issue date: 2020.07.22/
Expiration date: 2024.05.26

Start of CE-marking: 2013.10

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

Sung Joon Choi