

Neobiotech Co.,LTD

EC Declaration of Conformity

Manufacturer : **Neobiotech Co., Ltd.**

#104, 24/#102,103,104-1,104-2,105,106,205,212,312,509, 510,511&10F,36,
Digital-ro 27gil, Guro-gu, Seoul, 08381, Korea

European representative : **DongBang Acuprime.**

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Product

Dental Titanium membrane : **CTi-mem System**

Classification : Class IIb by Rule 8 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC
Conformity Assessment Route : Annex II, Excluding Section 4, MDD 93/42/EEC as amended
by 2007/47/EC

We hereby declare that complies with the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) using Annex II as the conformity assessment procedure via SGS(NB 0120) as the Notified Body.

Applied standards;

- ISO 13485:2003 Medical devices – Quality management system – Requirements for regulatory purposes
- EN ISO 14971 :2012 Medical devices - Application of Risk management to medical devices
- ISO 14630:2008 Non-active surgical implants - General requirements
- EN 1642:2011 Dentistry – Medical device for dentistry – Dental implant
- ISO11137-1: 2006 Sterilization of health care products – Radiation –Part 1 : Requirements for development, validation and routine control of a sterilization process for medical devices

Notified Body: SGS United Kingdom International Certification Services Limited
Unit 202B, Worle Parkway Weston-Super-Mare North Somerset
BS 22 OWA United Kingdom

Start of CE-marking :

#104, 24/#102,103,104-1,104-2,105,106,205,212,312,509, 510,511&10F,36,
Digital-ro 27gil, Guro-gu, Seoul, 08381, Korea on Jan, 19th, 2017

Signature :


President on behalf of
Neobiotech Co., Ltd

- Attachment – Product schedule

Product Schedule

A. Neo Titanium mesh/CTi-mem Series

1. Neo Titanium mesh Series

TMN 122004	RTMN1220125
TMN 202504	RTMN2025125
TMN 253504	RTMN2535125
TMN 355004	RTMN3550125
TMN 122008	
TMN 202508	
TMN 253508	
TMN 355008	

2. CTi-mam Series

ATMBN 0810S	ATMBN 0910L	ATMLN 0910L	CTM 1215
ATMBN 0912S	ATMBN 0912L	ATMLN 0912L	CTM 1220
ATMBN 0915S	ATMBN 0915L	ATMLN 0915L	CTM 1520
	PTMBN 1210S	PTMLN 1210S	
	PTMBN 1212S	PTMLN 1212S	
	PTMBN 1215S	PTMLN 1215S	
	PTMBN 1210L	PTMLN 1210L	
	PTMBN 1212L	PTMLN 1212L	
	PTMBN 1215L	PTMLN 1215L	

ATUBN 0910L	CTM 1215F	RATMB0810F	EZTM1210B4
ATUBN 0912L	CTM 1220F	RATMB0912F	EZTM1212B5
ATUBN 0915L	CTM 1520F	RATMB0915F	EZTM1215B6
PTUBN 1210S	CTM 2023F	EZTM0810A1	
PTUBN 1212S	CTM 2530F	EZTM0912A2	
PTUBN 1215S		EZTM0915A3	
ATMBN 0915SF		RPTMB1210SF	
PTMBN 1215LF		RPTMB1212SF	
PTMLN 1215LF		RPTMB1215SF	
RPTML0910F	EZTM0910C1	RCTM1215	
RPTML0912F	EZTM0912C2	RCTM1220	
RPTML0915F	EZTM0915C3	RCTM1525	
RPTML1210SF	EZTM1210C4		
RPTML1212SF	EZTM1212C5		
RPTML1215SF	EZTM1215C6		
RPTML1210LF	EZTM1210C7		
RPTML1212LF	EZTM1212C8		
RPTML1215LF	EZTM1215C9		

B. Fixing Screw

MFS1602	MFS1604	MFS1606	MFS2003
MFS1603	MFS1605	MFS1607	MFS2005
MFSSET01			MFS2007

C. Tent Screw

CTS2007	CTS2507	CTSSET01
CTS2008	CTS2508	CTSSET02
CTS2010	CTS2510	CTSSET03
CTS2011	CTS2511	CTSSET04
CTS2013	CTS2513	
CTS2015	CTS2515	
CTS2018	CTS2518	
CTS2020	CTS2520	
	CTCS30	

D. EZ-Fixing Screw

EZFS1703CP	EZFS1703C
EZFS1705CP	EZFS1705C
EZFS1707CP	EZFS1707C
EZFS1710CP	EZFS1710C
EZFS1713CP	EZFS1713C
EZFS1715CP	EZFS1715C
EZFCC06P	