

## Neobiotech Co.,LTD

### EC Declaration of Conformity

Manufacturer : **Digital Business Division.**

1F, Middle 2F, 13, Digital-ro 27-gil, Guro-Gu, Seoul ,08382, Korea

European representative: DongBang Acuprime

1 Forrest Units, Hennock Road East, Marsh Barton, Exeter EX2 8RU, U.K

Tel : +44 1392 829500 Fax: +44 1392 823232

**Product: Zirconia Block**

**Model/Type : CAMEleon Zirconia Block**

Classification: **Class IIa** by Rule 8 of Annex IX, MDD **93/43/EEC** as amended by 2007/47/EC

Conformity Assessment Route: Annex II, Excluding Section 4, MDD 93/43/EEC as amended  
by 2007/47/EC

We hereby declare that complies with the Medical Devices Directive 93/43/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;

- EN ISO 13485:2012 Medical devices – Quality management system – Requirements for Regulatory purposes
- EN ISO 14971:2012 Medical devices - Application of Risk management to medical devices
- EN 1641:2009 Dentistry - Medical devices for dentistry – Materials
- EN ISO 13356:2013 Implants for surgery. Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)
- EN ISO 6872:2008 Dentistry – Ceramic materials
- EN ISO 9693:2000 Metal-Ceramic Dental Restorative Systems
- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

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:

Place, Date of issue : Neobiotech Co., Ltd. Digital business division.

1F, Middle 2F, 13, Digital-ro 27-gil, Guro-Gu, Seoul ,08382, Korea

On Jan 19th, 2017

Signature:



President on behalf of  
Neobiotech Co., Ltd

# Product Schedule

## **B Type**

DT BA Series

: DT BA-14

DT BB Series

: DT BB-14, DT BB-16

DT BC Series

: DT BC-12, DT BB-14, DT BB-16, DT BB-18

DT BD Series

: DT BD-16, DT BD-18, DT BD-20

DT BE Series

: DT BE-12, DT BE-14, DT BE-16, DT BE-18, DT BE-20, DT BE-22

DT BDR Series

: DT BER-10, DT BER-12, DT BER-14, DT BER-16, DT BER-18, DT BER-20, DT BER-22, DT BER-25

DT BOR Series

: DT BOR-10, DT BOR-12, DT BOR-14, DT BOR-16, DT BOR-18, DT BOR-20, DT BOR-25

DT BWR Series

: DT BWR-10, DT BWR-12, DT BWR-14, DT BWR-16, DT BWR-18, DT BWR-20, DT BWR-25

DT BZR Series

: DT BZR-10, DT BZR-12, DT BZR-14, DT BZR-16, DT BZR-18, DT BZR-20, DT BZR-22, DT BZR-25

## **S Type**

DT SA Series

: DT SA-14

DT SB Series

: DT SB-14, DT SB-16

DT SC Series

: DT SC-12, DT SC-14, DT SC-16, DT SC-18

DT SD Series

: DT SD-16, DT SD-18, DT SD-20

DT SE Series

: DT SE-12, DT SE-14, DT SE-16, DT SE-18, DT SE-20, DT SE-22, DT SE-24, DT SE-26

DT SDR Series

: DT SDR-10, DT SDR-12, DT SDR-14, DT SDR-16, DT SDR-18, DT SDR-20, DT SDR-22, DT SDR-24,  
DT SDR-25

DT SOR Series

: DT SOR-10, DT SOR-12, DT SOR-14, DT SOR-16, DT SOR-18, DT SOR-20, DT SOR-22, DT SOR-25

DT SWR Series

: DT SWR-10, DT SWR-12, DT SWR-14, DT SWR-16, DT SWR-18, DT SWR-20, DT SWR-22,

DT SWR-25

DT SZR Series

: DT SZR-10, DT SZR-12, DT SZR-14, DT SZR-16, DT SZR-18, DT SZR-20, DT SZR-22, DT SZR-25

## **ET Type**

DT ETA Series

: DT ETA-14

DT ETB Series

: DT ETB-14, DT ETB-16

DT ETC Series

: DT ETC-12, DT ETC-14, DT ETC-16, DT ETC-18

DT ETD Series

: DT ETD-16, DT ETD-18, DT ETD-20

DT ETE Series

: DT ETE-12, DT ETE-14, DT ETE-16, DT ETE-18, DT ETE-20, DT ETE-22, DT ETE-24, DT ETE-26

DT ETDR Series

: DT ETDR-10, DT ETDR-12, DT ETDR-14, DT ETDR-16, DT ETDR-18, DT ETDR-20, DT ETDR-22,

DT ETDR-25

DT ETOR Series

: DT ETOR-10, DT ETOR-12, DT ETOR-14, DT ETOR-16, DT ETOR-18, DT ETOR-20, DT ETOR-22,

DT ETOR-25

DT ETWR Series

: DT ETWR-10, DT ETWR-12, DT ETWR-14, DT ETWR-16, DT ETWR-18, DT ETWR-20, DT ETWR-22,

DT ETWR-25

DT ETZR Series

: DT ETZR-10, DT ETZR-12, DT ETZR-14, DT ETZR-16, DT ETZR-18, DT ETZR-20, DT ETZR-22,

DT ETZR-25

## **SA Type**

DT SA1A Series

: DT SA1A-14

DT SA2A Series

: DT SA2A-14

DT SA3A Series

: DT SA3A-14

DT SA1B Series

: DT SA1B-14, DT SA1B-16

DT SA2B Series

: DT SA2B-14, DT SA2B-16

DT SA3B Series

: DT SA3B-14, DT SA3B-16

DT SA1C Series

: DT SA1C-12, DT SA1C-14, DT SA1C-16, DT SA1C-18

DT SA2C Series

: DT SA2C-12, DT SA2C-14, DT SA2C-16, DT SA2C-18

DT SA3C Series

: DT SA3C-12, DT SA3C-14, DT SA3C-16, DT SA3C-18

DT SA1D Series

: DT SA1D-16, DT SA1D-18, DT SA1D-20

DT SA2D Series

: DT SA2D-16, DT SA2D-18, DT SA2D-20

DT SA3D Series

: DT SA3D-16, DT SA3D-18, DT SA3D-20

DT SA1E Series

: DT SA1E-12, DT SA1E-14, DT SA1E-16, DT SA1E-18, DT SA1E-20, DT SA1E-22, DT SA1E-24,  
DT SA1E-26

DT SA2E Series

: DT SA2E-12, DT SA2E-14, DT SA2E-16, DT SA2E-18, DT SA2E-20, DT SA2E-22, DT SA2E-24,  
DT SA2E-26

DT SA3E Series

: DT SA3E-12, DT SA3E-14, DT SA3E-16, DT SA3E-18, DT SA3E-20, DT SA3E-22, DT SA3E-24,  
DT SA3E-26

DT SA1DR Series

: DT SA1DR-10, DT SA1DR-12, DT SA1DR-14, DT SA1DR-16, DT SA1DR-18, DT SA1DR-20,  
DT SA1DR-22, DT SA1DR-25

DT SA2DR Series

: DT SA2DR-10, DT SA2DR-12, DT SA2DR-14, DT SA2DR-16, DT SA2DR-18, DT SA2DR-20,  
DT SA2DR-22, DT SA2DR-25

DT SA3DR Series

: DT SA3DR-10, DT SA3DR-12, DT SA3DR-14, DT SA3DR-16, DT SA3DR-18, DT SA3DR-20,  
DT SA3DR-22, DT SA3DR-25

DT SA1OR Series

: DT SA1OR-10, DT SA1OR-12, DT SA1OR-14, DT SA1OR-16, DT SA1OR-18, DT SA1OR-20,  
DT SA1OR-22, DT SA1OR-25

DT SA2OR Series

: DT SA2OR-10, DT SA2OR-12, DT SA2OR-14, DT SA2OR-16, DT SA2OR-18, DT SA2OR-20,  
DT SA2OR-22, DT SA2OR-25

DT SA3OR Series

: DT SA3OR-10, DT SA3OR-12, DT SA3OR-14, DT SA3OR-16, DT SA3OR-18, DT SA3OR-20,  
DT SA3OR-22, DT SA3OR-25

DT SA1WR Series

: DT SA1WR-10, DT SA1WR-12, DT SA1WR-14, DT SA1WR-16, DT SA1WR-18, DT SA1WR-20,  
DT SA1WR-22, DT SA1WR-25

DT SA2WR Series

: DT SA2WR-10, DT SA2WR-12, DT SA2WR-14, DT SA2WR-16, DT SA2WR-18, DT SA2WR-20,  
DT SA2WR-22, DT SA2WR-25

DT SA3WR Series

: DT SA3WR-10, DT SA3WR-12, DT SA3WR-14, DT SA3WR-16, DT SA3WR-18, DT SA3WR-20,  
DT SA3WR-22, DT SA3WR-25

DT SA1ZR Series

: DT SA1ZR-10, DT SA1ZR-12, DT SA1ZR-14, DT SA1ZR-16, DT SA1ZR-18, DT SA1ZR-20,  
DT SA1ZR-22, DT SA1ZR-25

DT SA2ZR Series

: DT SA2ZR-10, DT SA2ZR-12, DT SA2ZR-14, DT SA2ZR-16, DT SA2ZR-18, DT SA2ZR-20,  
DT SA2ZR-22, DT SA2ZR-25

DT SA3ZR Series

: DT SA3ZR-10, DT SA3ZR-12, DT SA3ZR-14, DT SA3ZR-16, DT SA3ZR-18, DT SA3ZR-20,  
DT SA3ZR-22, DT SA3ZR-25