



Declaration of Conformity

Elephant Dental B.V. declares, that under our sole responsibility, our

Dental PM Alloys

meet the relevant provisions of the European Medical Device Directive 93/42/EEC and amendments up to and including 2007/47/EC for products class IIa. (See product list).

Our products are covered by the CE-certificate number 2110131CE01, revised and released at April 01, 2011 by DEKRA Certification, The Netherlands, with Notified Body Identification Number 0344.

Previously our products were covered by the CE-certificate number 2110131CE01, reissued and released at November 01, 2010 by KEMA Certification, The Netherlands, with the same Notified Body Identification Number 0344.

Earlier the products were covered by certificates issued by TNO Certification, The Netherlands, Notified Body Identification Number 0336 first issued and released at October 6, 1995, this contract ended October 16, 2007.

Our Quality Management System is a certified Quality System according to EN-ISO 9001:2008, ISO 9001: 1994 was first issued and released at March 25, 1996 and EN-ISO 13485:2003, ISO 13485:1966 was first issued and released at November 1, 2003

Elephant Dental B.V.

T.J. Grinwis
Quality Assurance Director

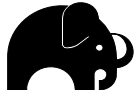
Hoorn, July14, 2011

Elephant Dental B.V.
Verlengde Lageweg 10
1628 PM Hoorn
The Netherlands





Carrara System		
Carrara PdF		540406050
Cera H		540106100
Cera F		540306120
Cera R Plus		540306030
Cera E		540706021
Cera Aurum		540306131
Cera Star		540306140
Gold ceramic alloys		
BioGold Plus		540406040
BioGold AN		540406030
BioGold Interaction		540406110
Bermudent Y		540406020
Bermudent H		540406010
Orion GX		540406060
Orion UX		540406080
Orion UX Plus		540406090
Orion UWX		540406070
Orion WX		540606020
Orion E		540606030
Orion Yellow		*540406140
Gold-palladium ceramic alloys		
Orion Vesta		540706070
Orion Isis Plus		540706050
Orion Isis		540706040
Orion Delphi		540606010
Palladium-silver ceramic alloys		
Orion Argos		540706010
Gold-platinum casting alloys		
Biolife PCF		540106170
Biolife 4		540106080
Apollo IST		540106010
Apollo 3		540106020
Apollo 3 PdF		540106030
Apollo 4		540106040
Apollo 4 PdF		540106070
Apollo 4 CF		540106060
Apollo 4 H		540106050



Casting alloys with reduced gold content		
Pluto 3		540106120
Pluto 4		540106130
Minerva 58		540206030
Minerva 4 PdF		540206050
Minerva 4 CF		540206040
Gold-palladium-silver casting alloys		
Pallacon		540306080
Pallium 3 C		540306090
Pallium 3		540306100