



Declaration of Conformity

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

Dental Solders and Laserwires

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, reissued and released at November 01, 2010 by KEMA Certification, The Netherlands, Notified Body Identification Number 0344.

Previously 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 first issued and released at March 29, 2005.

Elephant Dental B.V.

T.J. Grinwis
Quality Assurance Director

Hoorn, November 01, 2010

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





ELEPHANT DENTAL QMS
DECLARATION OF CONFORMITY

CED 2/3
VERSIE: 2
Rev. datum: 01-nov-2010

Laserwires Ø 0,4 mm		
Bermudent H		543503290
Bermudent Y		543503300
BioGold AN		543503310
BioGold Plus		543503320
BioLife 4		543503080
BioLife PCF		543503470
Carrara PdF		543503330
Cera Aurum		543503520
Cera E		543503410
Cera F		543503490
Cera H		543503100
Cera R Plus		543503220
Orion Argos		543503400
Orion E		543503480
Orion GX		543503340
Orion UWX		543503350
Orion UX		543503360
Orion UX Plus		543503370
Orion Vesta		543503440
Orion WX		543503390
Apollo 3 PdF		543503030
Apollo 4		543503040
Apollo 4 CF		543503060
Apollo 4 H		543503050
Apollo 4 PdF		543503070
Apollo IST		543503010
Minerva 4 CF		543503170
Minerva 4 PdF		543503180
Minerva 58		543503160
Orion Isis Plus		543503420
Pallium 3		543503270
Pallium 3C		543503280
Pluto 3		543503120
Pluto 4		543503130
Laserwires Ø 0,6 mm		
BioGold Plus		544003320
Carrara PdF		544003330
Cera Aurum		544003520
Cera F		544003490



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Cera R Plus		544003220
Orion Virgo Plus		544003450
Cera E		544003410
Solders		
Carrara 750		542003012
Carrara 750		542503012
Carrara 950		542003013
Carrara 950		542503013
Elephant I 850		542003001
Elephant I 850		542503001
Elephant II PdF 800		542003005
Elephant II PdF 800		542503005
Elephant III PdF 750		542003006
Elephant III PdF 750		542503006
Elephant IV PdF 700		542003007
Elephant IV PdF 700		542503007
GNP 800		542503022
GNP 930		542003008
GNP 930		542503008
Orion 1030 PdF geel		542003015
Orion 1030 PdF geel		542503015
Orion 1060 geel		542003016
Orion 1060 geel		542503016
Orion 1090 wit		542003019
Orion 1090 wit		542503019
Orion 1120 wit		542003020
Orion 1120 wit		542503020
Pallas III 750		542003011
Pallas III 750		542503011
Denti-Lot		7672601005
Witex-Lot		7670538000