



## Declaration of Conformity

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

### Dental NP 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, 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 13485:1996 was first issued and released at November 1, 2003.

Elephant Dental B.V.

T.J. Grinwis  
Quality Assurance Director

Hoorn, July 14, 2011

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





ELEPHANT DENTAL QMS  
DECLARATION OF CONFORMITY

CED 2/2  
VERSIE: 3  
Rev. datum: 14-JUL-2011

<b>Vi-Comp LFC</b>		
Ceramic alloy for low fusing ceramic s.a. Carrara Interaction		
Vi-Comp LFC	250 g	005010055
<b>Wisil</b>		
Cobalt based dental casting alloy for removable restorations		
Wisil, ingots of 8.5 g	1 kg	7610517020
Wisil M, ingots of 8.5 g	1 kg	7610517021
Wisil M Plus, ingots of 8.5 g	1 kg	7610517022
Wisil D, ingots of 8.5 g	1 kg	7610517029
<b>Chromodur</b>		
Cobalt based dental casting alloy for removable restorations		
Chromodur ingots of 8.5 g	1 kg	7610518008
Chromodur M, ingots of 8.5 g	1 kg	7610518009
<b>Crutanium</b>		
Cobalt based dental casting alloy for removable restorations		
Ingots of 20 g	1 kg	7610520000
Ingots of 30 g	500 g	7610520050
<b>Supranium</b>		
Nickel based dental metal-ceramic alloy		
Ingots of 6 g	500 g	7610517010