



Declaration of Conformity

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

Dental Wires

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 are 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, October 21, 2011

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





ELEPHANT DENTAL QMS
DECLARATION OF CONFORMITY

CED 2/4
VERSIE: 3
Rev. datum: 14-jul-2011

| Apollo D wire | | |
|---------------------------------|------|------------|
| Apollo D Rond 0,7 | | 543001190 |
| Apollo D Rond 0,8 | | 543001180 |
| Apollo D Rond 0,9 | | 543001170 |
| Apollo D Rond 1,0 | | 543001160 |
| Apollo D Rond 1,1 | | 543001150 |
| Apollo D Rond 1,2 | | 543001140 |
| Apollo D Rond 1,3 | | 543001130 |
| Apollo D Rond 1,4 | | 543001120 |
| Apollo D Rond 1,5 | | 543001110 |
| Apollo D Rond 1,15 | | 543001145 |
| Apollo D Half rond 1,5 | | 543101040 |
| Apollo D Half rond 1,8 | | 543101010 |
| | | |
| Apollo R wire | | |
| 0,25 mm | | 542903040 |
| 0,35 mm | | 542903030 |
| | | |
| Pernox wire | | |
| 0,70 mm | | 543201190 |
| 0,90 mm | | 543201170 |
| 1,00 mm | | 543201160 |
| 1,10 mm | | 543201150 |
| 1,20 mm | | 543201140 |
| 1,30 mm | | 543201130 |
| 1,40 mm | | 543201120 |
| 1,50 mm | | 543201110 |
| 1,80 mm | | 543201080 |
| | | |
| Wipla wire - round, soft | | |
| 0.25 mm | 75 m | 6100104025 |
| 0.30 mm | 70 m | 6100104030 |
| 0.35 mm | 65 m | 6100104035 |
| 0.40 mm | 60 m | 6100104040 |
| 0.50 mm | 50 m | 6100104050 |
| 0.80 mm | 20 m | 6100104080 |
| 0.90 mm | 10 m | 6100104090 |
| 1.00 mm | 10 m | 6100104100 |
| 1.10 mm | 9 m | 6100104110 |
| 1.20 mm | 8 m | 6100104120 |
| 1.30 mm | 8 m | 6100104130 |
| 1.50 mm | 10 m | 6100104150 |



| | | |
|--|--------|------------|
| Wipla wire - round, hard | | |
| 0.70 mm | 30 m | 6100106070 |
| 0.80 mm | 20 m | 6100106080 |
| 0.90 mm | 10 m | 6100106090 |
| 1.00 mm | 10 m | 6100106100 |
| 1.20 mm | 8 m | 6100106120 |
| Wipla wire - round, spring tempered | | |
| 0.30 mm | 70 m | 6100108030 |
| 0.40 mm | 60 m | 6100108040 |
| 0.50 mm | 50 m | 6100108050 |
| 0.60 mm | 40 m | 6100108060 |
| 0.70 mm | 30 m | 6100108070 |
| 0.80 mm | 20 m | 6100108080 |
| 0.90 mm | 10 m | 6100108090 |
| 1.00 mm | 10 m | 6100108100 |
| 1.10 mm | 9 m | 6100108110 |
| 1.20 mm | 8 m | 6100108120 |
| 1.30 mm | 8 m | 6100108130 |
| Wipla wire - half-round, hard | | |
| 0.65 x 1.30 mm | 10 m | 6100112065 |
| 0.75 x 1.50 mm | 9 m | 6100112075 |
| 0.87 x 1.75 mm | 8 m | 6100112087 |
| 1.00 x 2.00 mm | 10 m | 6100112100 |
| 1.50 x 3.00 mm | 10 m | 6100112150 |
| Wipla wire - oval, hard | | |
| 1.40 x 2.50 mm | 10 m | 6100116140 |
| Titan laser welding wire | | |
| ∅ 0.25 mm | 2 m | 6279950505 |
| ∅ 0.50 mm | 2 m | 6279950506 |
| Vitallium laser welding wire | | |
| ∅ 0.50 mm 7 pieces | 250 mm | 8041100 |
| ∅ 0.35 mm | 2 m | 8041135 |
| ∅ 0.50 mm | 2 m | 8041150 |



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| Wiptam wire - round | | |
|---------------------------------|--|------------|
| 0.70 mm | | 7600141070 |
| 0.90 mm | | 7600141090 |
| 1.00 mm | | 7600141100 |
| 1.10 mm | | 7600141110 |
| 1.20 mm | | 7600141120 |
| 1.30 mm | | 7600141130 |
| 1.50 mm | | 7600141150 |
| | | |
| Wiptam wire - half-round | | |
| 0.75 x 1.30 mm | | 7600142075 |
| 0.87 x 1.50 mm | | 7600142087 |
| 1.00 x 2.00 | | 7600142100 |