

# Certification of International Materials Conformity Legal Adherence to EU Nickel Directive ( 76 / 769 / EEC )

Wildcat Collection body piercing products have been tested by independent analytical laboratories and their integrity is proven to be in accordance with the terms of the EU Nickel Directive. This information sheet reproduces original test certificates indicating our compliance with European regulations.

The EU Nickel Directive, which entered EU Law as of 1st July 2001, required that nickel content used in parts during epithelization after piercing must contain less than 0.05% nickel by mass. Certificates reproduced in this document show our Implantanium® and titanium jewellery is well below these limits.

Annex 2 of the directive demanded that objects intended for direct and prolonged contact with the skin must have a nickel release below 0.5 microgrammes per cm<sup>2</sup> per week. Certificates reproduced here show that our stainless steel, titanium and Implantanium® jewellery is well within this criteria and is legal for all primary and secondary piercing applications.

## AMMENDMENT TO EU NICKEL DIRECTIVE

An important change has been adopted by all EU member states to Directive 76/769/EEC.

The following paragraph has now been DELETED from the Directive :

"Nickel and its compounds may not be used in post assemblies which are inserted into ears and other pierced parts of the human body during epithelization of the wound caused by the piercing, whether subsequently removed or not, unless such post assemblies are homogeneous and the concentration of nickel-expressed as a mass of nickel to total mass-is less than 0.05%"

## Titanium and Implantanium®

### Annex 1 of the Nickel Directive states:

"Nickel may not be used in post assemblies unless the posts are homogenous and the concentration of nickel is less than 0.05% (500 parts per million)."

The following certificate confirms that Wildcat titanium and Nickel negative® Implantanium® can be legally used for initial piercing procedures and for periods of epithelization of the wound.

### Annex 2 of the Nickel Directive stated

"Products intended to come into direct and prolonged contact with the skin cannot be used if the nickel release from the parts coming into contact with the skin is greater than 0.5 microgrammes per cm<sup>2</sup> per week."

The following certificates confirm that elution tests on Wildcat stainless steel, titanium and Implantanium® jewellery satisfy the requirements of the EU Nickel Directive and can be used indefinitely for all secondary piercing applications worldwide.



Report No. 05000/01 Issued: 08/06/00 Reprinted: 12/06/00


| DATE-S/N         | REFERENCE  | ELEMENT                  | RESULT                    | METHOD  |
|------------------|------------|--------------------------|---------------------------|---------|
| 24/05/00<br>0062 | IMP RING   | Nickel<br>~Ball<br>~Ring | -----<br>298ppm<br>346ppm | ICP-OES |
| 24/05/00<br>0063 | Ti RING    | Nickel<br>~Ring          | -----<br>107ppm           | ICP-OES |
| 24/05/00<br>0064 | Ti BARBELL | Nickel<br>~Ball<br>~Bar  | -----<br>93ppm<br>125ppm  | ICP-OES |

Elution results reported as microgrammes/cm<sup>2</sup>/week.  
Note: tested to BSEN1811 including BSEN12472.

Signature: C D Jarvis  
F M Hudson

- \* 0062 Imp Ring: Both ball and ring tested for nickel mass
- \* 0063 Ti Ring: Ring tested for nickel mass
- \* 0064 Ti Barbell: Both ball and bar tested for nickel mass

Nickel negative® and Implantanium® are internationally Registered Trademarks of The Wildcat Collection



Report No. 05002/02 Issued: 04/07/00 Extracts

| DATE-S/N         | REFERENCE | ELEMENT                      | RESULT                        | METHOD          |
|------------------|-----------|------------------------------|-------------------------------|-----------------|
| 13/06/00<br>0075 | BE16R     | Ni Elution<br>~Ball<br>~Hoop | -----<br><0.1<br><0.1<br>Pass | Elution<br>Test |

| DATE-S/N         | REFERENCE | ELEMENT                     | RESULT                        | METHOD          |
|------------------|-----------|-----------------------------|-------------------------------|-----------------|
| 13/06/00<br>0076 | VHBC      | Ni Elution<br>~Bar<br>~Hoop | -----<br><0.1<br><0.1<br>Pass | Elution<br>Test |

| DATE-S/N         | REFERENCE | ELEMENT                     | RESULT                        | METHOD          |
|------------------|-----------|-----------------------------|-------------------------------|-----------------|
| 13/06/00<br>0077 | MMLA      | Ni Elution<br>~Ball<br>~Pin | -----<br><0.1<br><0.1<br>Pass | Elution<br>Test |

| DATE-S/N         | REFERENCE | ELEMENT                      | RESULT                        | METHOD          |
|------------------|-----------|------------------------------|-------------------------------|-----------------|
| 13/06/00<br>0078 | BE 2R     | Ni Elution<br>~Ball<br>~Hoop | -----<br><0.1<br><0.1<br>Pass | Elution<br>Test |

Elution results reported as microgrammes/cm<sup>2</sup>/week.  
Note: tested to BSEN1811 including BSEN12472.

Signature: C D Jarvis  
F M Hudson

The above 4 certificates cover Wildcat surgical stainless steel body jewellery manufactured from three different sources.

**Nickel Release: Titanium and Implantanium®**

The following three certificates confirm the integrity of Wildcat titanium and implantanium® in conforming to Annex 2 of the EU Nickel Directive.



Report No. 05002/02 Issued: 04/07/00 Extracts

| DATE-S/N         | REFERENCE    | ELEMENT                      | RESULT                        | METHOD          |
|------------------|--------------|------------------------------|-------------------------------|-----------------|
| 13/06/00<br>0071 | IMPLANTANIUM | Ni Elution<br>~Ball<br>~Hoop | -----<br><0.1<br><0.1<br>Pass | Elution<br>Test |

| DATE-S/N         | REFERENCE  | ELEMENT                     | RESULT                        | METHOD          |
|------------------|------------|-----------------------------|-------------------------------|-----------------|
| 13/06/00<br>0074 | Ti BARBELL | Ni Elution<br>~Ball<br>~Bar | -----<br><0.1<br><0.1<br>Pass | Elution<br>Test |

| DATE-S/N         | REFERENCE | ELEMENT                 | RESULT                | METHOD          |
|------------------|-----------|-------------------------|-----------------------|-----------------|
| 13/06/00<br>0073 | Ti RING   | Ni Elution<br>Ring/Hoop | -----<br><0.1<br>Pass | Elution<br>Test |

Elution results reported as microgrammes/cm2/week.  
Note: tested to BSEN1811 including BSEN12472.

Signature: C D Jarvis  
F M Hudson

**Blackline Biocompatibility:**

(Tripartite Protocol for Materials That Experience Body Contact):

|                                |   |
|--------------------------------|---|
| SENSITISATION:                 | Non Sensitising (No Delayed Dermal Contact Sensitisation) |
| Cytotoxicity:                  | Non-Toxic (No evidence of Causing Cell Lysis)             |
| Acute Systemic Toxicity (T12): | Non Toxic   |
| Intracutaneous Toxicity (T13): | No Tissue Reaction  |
| Mutagenicity / Genotoxicity:   | Non-Mutagenic   |
| USP Muscle Implantation (T14): | Non-Irritating To Muscle Tissue                           |
| Hemolysis:                     | Non-Hemolytic, Compatible with Blood                      |

**Zirconium Nitride Biocompatibility:**

(Tripartite Protocol for Materials That Experience Body Contact):

|                                |   |
|--------------------------------|---|
| SENSITISATION:                 | Non Sensitising (No Delayed Dermal Contact Sensitisation) |
| Cytotoxicity:                  | Non-Toxic (No evidence of Causing Cell Lysis)             |
| Acute Systemic Toxicity (T12): | Non Toxic   |
| Intracutaneous Toxicity (T13): | No Tissue Reaction  |
| Mutagenicity / Genotoxicity:   | Non-Mutagenic   |
| USP Muscle Implantation (T14): | Non-Irritating To Muscle Tissue                           |
| Hemolysis:                     | Non-Hemolytic, Compatible with Blood                      |

**ВДТФОНЕНВАФД ПЕ ПТИЖНО  
CERTIFICATE OF ORIGIN**

The Mammoth Ivory covered by this document is part of a shipment of 601.5 kg of mammoth tusks shipped by LLC "EKSPONIRAMOTIVNY" from Moscow to agents of The Wildcat Collection in the European Union in accordance with the contract #92-0685287/0100 of 16/12/98 and are of origin of the Russian Federation.

Moscow 21/06/99



A. A. Yusipov

M. B. Karpov

The Russian Chamber of Commerce and Industry confirms hereby that the goods mentioned above are really of origin of the Russia.

The Russian Chamber of Commerce and Industry

Moscow 21/06/99



Form with fields for Name, Address, Telephone, Fax, and other contact information. Includes a section for 'Date of Receipt' and 'The Chamber of Commerce and Industry'.

