



Corporate Office  
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### Bionix Development Corporation

### EC DECLARATION OF CONFORMITY



According to annex VII of the Council Directive 93/42/EEC concerning medical devices

Bionix Development Corporation  
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USA

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declare under our sole responsibility that the following non-sterile products under Class I:

Enteral Feeding Tube DeClogger:

- |                      |                       |                      |
|----------------------|-----------------------|----------------------|
| 911 – Blue 12-14 Fr  | 912 – Yellow 16-18 Fr | 913 – Green 20-22 Fr |
| 921 – Brown 12-16 Fr | 922 – Orange 18-22 Fr | 935 – Starter Kit    |

meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them.

The products are intended to be used as single use disposable devices for clearing and prevention of feeding tube blockage.

Conformity assessment was performed according to Article II (5), Annex VII Section 3.

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Obelis s.a. 34 Av. de Tervuren  
B-1040 Brussels, Belgium  
Phone: 32.2.732.59.54  
Fax: 32.2.732.60.03  
E-mail: [mail@obelis.net](mailto:mail@obelis.net)  
Representative: Mr. Gideon ELKAYAM

Toledo, OH 11-8-02  
Issue place and date

Signature  
James Vehslage  
C.O.O.