**Corporate Office**
5154 Enterprise Blvd., Toledo, Ohio 43612
Phone 419.727.8421 • Fax 419.727.8426

# Bionix Development Corporation

## EC DECLARATION OF CONFORMITY

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

Bionix Development Corporation
5154 Enterprise Boulevard
Toledo, OH 43612
USA

Phone: 419-727-8721
Fax: 419-727-4430
E-mail: bionix@bionix.com

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

Safe Ear Curettes:

| | | |
|---|---|---|
| 1222 – Green MicroLoop | 2999 – Orange ControLoop | 3444 – Red AngleLoop |
| 4111 – Purple VersaLoop | 4888 – Blue InfantScoop | 5444 – Small/Youth Kit |
| 5888 – Large/Adult Kit | 6333 – Yellow CeraSpoon | 9555 – White FlexLoop |

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

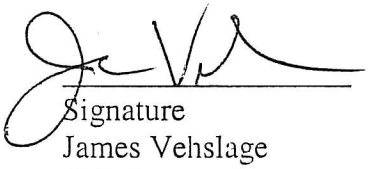
The products are intended to be used as single use disposable ear curettes for cerumen removal.

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
Representative: Mr. Gideon ELKAYAM

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


Signature
James Vehslage
C.O.O.