



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:

Disposable Nasal Speculum:
9877 – 20 count 9878 – 48 count

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

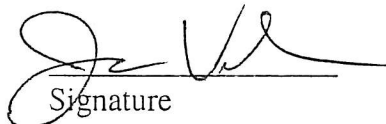
The products are intended to be used as single use disposable nasal specula for opening
and visualization of the nasal cavity.

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.