Bionix Development Corp.

EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC, concerning medical devices

We

Bionix Development Corp.
5154 Enterprise Blvd.
Toledo, OH 43612-3807

declare under our sole responsibility that the following non-sterile products under Class I meet the provisions of the Council Directive 93/42/EEC, as amended by the Council directive 2007/47/EC, concerning medical devices which apply to them:

Lighted Ear Curettes consisting of:

2210 Lighted AngleLoop
2201 Lighted AngleLoop Clinic Pack
2230 Lighted Wave Curette
2203 Lighted Wave Curette Clinic Pack
2250 Lighted CeraSpoon
2205 Lighted CeraSpoon Clinic Pack
2270 Lighted VersaLoop
2207 Lighted VersaLoop Clinic Pack
2245 Lighted Variety Pack
2209 Lighted Variety Pack Clinic Pack
2220 Lighted MicroLoop
2202 Lighted MicroLoop Clinic Pack
2240 Lighted FlexLoop
2204 Lighted FlexLoop Clinic Pack
2260 Lighted InfantScoop
2206 Lighted InfantScoop Clinic Pack
2280 Lighted CeraPik
2208 Lighted CeraPik Clinic Pack
2750 Lighted Forceps
2511 Lighted Articulating Curette

The product is intended to be used to safely and thoroughly clean the ear canal of wax and debris.

Conformity assessment was performed according to Article 11 (5), Annex VII Section 3. Of the Council Directive 93/42/EEC as amended by the Council Directive 2007/47/EC.

The following standards were used to prove the products conformity with the essential requirements of the above directive:

EN ISO 9001:2008

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

Obelis s.a.
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B-1040 Brussels, Belgium

Toledo OH – February 2, 2018
Issue place and date

Daniel Brooks
Quality Assurance Manager