



Corporate Office
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Bionix Development Corporation

EC DECLARATION OF CONFORMITY

We,

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

hereby declare under our own responsibility that the following product(s):

1222 MicroLoop
3444 AngleLoop
6333 CeraSpoon
9555 FlexLoop
2750 Lighted Forcep

2999 ControLoop
4888 InfantScoop
8111 Articulating Curette
5777 Starter Kit

meet(s) the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them (it).

The abovementioned device(s) has(ve) been classified as class I devices according to rule I

This declaration is supported by the Quality Management System certification EN ISO 9001:2008 Certificate No. CERT-0064229 Issue date July 18 2012 Certificate Expiry Date Sept 8 2015 Issued by QMI-SAI Global

This declaration is based on the conformity assessment of products to the requirements of Annex(es) Article 11 (5), Annex VII Section 3 of the Council Directive 93/42/EEC.

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled "Manufacturer"

Toledo, Ohio USA (06/25/2014)
Issue place and date

European Authorized Representative:

Daniel Brooks
Quality Assurance Manager

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