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## **BIONIX DEVELOPMENT CORPORATION**

### **EC DECLARATION OF CONFORMITY**

We, Bionix Development Corporation hereby declare under our own responsibility that the following products:

a.) OtoClear SprayWash Kit.

b.) OtoClear Tips

meet the provisions of the Council Directive 93/42/EEC and the essential requirements which apply to them.

The abovementioned devices have been classified as class I, devices according to rules 1 and 5 of Annex IX of Council Directive 93/42/EEC.

This declaration is supported by the Quality Management System certification ISO 9001:2008, with reference number of the Certificate CERT-0091139 issued bySAI Global Certification Services Pty Ltd, 680 George St, Level 37-38, Sydney, NSW, 2000, Australia.

This declaration is based on the conformity assessment of products to the requirements of Annex VII of Council Directive 93/42/EEC

We declare under our own responsibility that the listed product(s) in this declaration are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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

Toledo, OH USA

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