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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:

referred to in the Annex to EC Declaration of Conformity 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 by SAI 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
Issue place and date (08/09/16)

European Authorized Representative:


Daniel Brooks
2016.09.08
10:28:00 -04'00'

Daniel Brooks
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Representative: Mr. Gideon ELKAYAM (CEO)



Annex to EC Declaration of Conformity

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

No.	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN code	Class*	Rule
1	OC-7290	OtoClear Spraywash Kit	Ear irrigation kit	Three streamed tip for ear irrigation.	62863	1	5
2	OC-7292	OtoClear Spraywash Kit without Basin	Ear irrigation kit	Three streamed tip for ear irrigation.	62863	1	5
3	SB-08050 SB-08100	ShotBlocker	Injection site desensitizer	Device to block needle poke pain associated with injections.	62733	1	1

* The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

Bionix Development Corp.

Daniel Brooks, QA & RA Manager

Signature: _____

Date: 08 September 2017

Stamp:

