

## **EU DECLARATION OF CONFORMITY**

Manufacturer name and address:	Bionix, LLC		
	1670 Indianwood Circle		
	Maumee, OH 43537 USA		
SRN (Single Registration Number):	US-MF-000020408		
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We, Bionix, LLC hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745.

The device(s) is/are Class 1 following Rule 5 of Annex VIII of REGULATION (EU) 2017/745.

The following conformity assessment procedure has been performed following Art. 19 and Art. 52 (7) and Tecchnical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

The following Standards have been used and in relation to which conformity is declared:

ISO 13485:2016 ISO 14971:2019

Toledo, OH USA 03/03/22

Issue place and date

Daniel Brooks

Director of Quality Assurance & Regulatory Affairs



## Annex - List of Devices Covered by the Declaration of Conformity

Щ	Commencial	Madal/	Description	ام مام مراجعا	Class	Cleasification	DACIO	
#	Commercial	Model/	Description	Intended	Class	Classification	BASIC	GMDN
	name/ Trade	Reorder/		Purpose		rule applied	UDI - DI	/EMDN
	name	Catalogue						code
		no.#						
	OtoClear Ear	7200ST	OtoClear	Single Use	1	5	859911004	65187
	Irrigation Tips		Single Use	tip for Ear			OtoClearN	
			Tips Bulk 5000 ct	Lavage			E	Z121490 99
			5000 Ct					99
	OtoClear	7270	Aquabot Kit,	Single Use	1	5	859911004	62863
	Powered by		20 tips	tip for Ear		5	OtoClearN	02000
	Aquabot Ear			Lavage			E	Z121490
	Irrigation Kit							99
	OtoClear	7275	Aqaubot Kit, 5	Single Use	1	5	859911004	62863
	Powered by	1210	tips	tip for Ear	1	C	OtoClearN	02003
	Aquabot Ear			Lavage			E	Z121490
	Irrigation Kit							99
	OtoClear 60cc	7235	60cc Luer	Single Use	1	5	859911004	62863
	Syringe		Lock Syringe Kit	tip for Ear Lavage			OtoClearN E	Z121490
			INC	Lavage			L	99
	OtoClear Ear	7200	Ear Irrigation	Single Use	1	5	859911004	65187
	Irrigation Tips		tips 40 ct	tip for Ear		-	OtoClearN	
				Lavage			E	Z121490
	OtoClear Ear	7202	Ear Irrigation	Single Use	1	5	859911004	99 65187
	Irrigation Tips	1202	tips 20 ct	tip for Ear		5	OtoClearN	03107
	· ·		-	Lavage			E	Z121490
								99
$\vdash$	OtoClear	7290	Spray Wash	Single Use	1	5	859911004	62863
	SprayWash Kit	1430	Kit w/20 tips	tip for Ear	1	Э	OtoClearN	02003
				Lavage			E	Z121490
			<b>~</b>					99
	OtoClear	7295	Spray Wash	Single Use	1	5	859911004	62863
	SprayWash Kit		Kit w/5 tips	tip for Ear Lavage			OtoClearN E	Z121490 99
	OtoClear Ear	701	Ear Irrigation	Single Use	1	5	859911004	62863
	Wax Removal		BHH	tip for Ear		5	OtoClearN	
				Lavage			E	Z121490
	Bionix Ear	3700	For Invinction	Dogin	4	F	050011004	99
	Irrigation	ə <i>1</i> 00	Ear Irrigation Basin	Basin used to catch	1	5	859911004 OtoClearN	42893
	Basins		Loubin	debris			E	A0699
				during ear				
				lavage				

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