



EU DECLARATION OF CONFORMITY

Manufacturer name and address:	Bionix, LLC 1670 Indianwood Circle Maumee, OH 43537 USA
SRN (Single Registration Number):	US-MF-000020408
Authorized Representative name and address (if applicable):	Obelis s.a. Bd. Général Wahis 53 B-1030 Brussels, Belgium Phone: 32.2.732.59.54 Fax: 32.2.732.60.03 E-mail: mail@obelis.net

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 Technical 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

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN /EMDN code
	OtoClear Ear Irrigation Tips	7200ST	OtoClear Single Use Tips Bulk 5000 ct	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	65187 Z121490 99
	OtoClear Powered by Aquabot Ear Irrigation Kit	7270	Aquabot Kit, 20 tips	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	62863 Z121490 99
	OtoClear Powered by Aquabot Ear Irrigation Kit	7275	Aquabot Kit, 5 tips	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	62863 Z121490 99
	OtoClear 60cc Syringe	7235	60cc Luer Lock Syringe Kit	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	62863 Z121490 99
	OtoClear Ear Irrigation Tips	7200	Ear Irrigation tips 40 ct	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	65187 Z121490 99
	OtoClear Ear Irrigation Tips	7202	Ear Irrigation tips 20 ct	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	65187 Z121490 99
	OtoClear SprayWash Kit	7290	Spray Wash Kit w/20 tips	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	62863 Z121490 99
	OtoClear SprayWash Kit	7295	Spray Wash Kit w/5 tips	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	62863 Z121490 99
	OtoClear Ear Wax Removal	701	Ear Irrigation BHH	Single Use tip for Ear Lavage	1	5	859911004 OtoClearN E	62863 Z121490 99
	Bionix Ear Irrigation Basins	3700	Ear Irrigation Basin	Basin used to catch debris during ear lavage	1	5	859911004 OtoClearN E	42893 A0699

