



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
Authorized Representative SRN (Single Registration Number):	BE-AR-000000106

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 28/04/22

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
	Safe Ear Currettes	1222	Safe Ear Curette Green MicroLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 SafeCurett esZF	65445 Q0399
	Safe Ear Currettes	2999	Safe Ear Curette Orange ControLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 SafeCurett esZF	65445 Q0399
	Safe Ear Currettes	3444	Safe Ear Curette Red AngleLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 SafeCurett esZF	65445 Q0399
	Safe Ear Currettes	4111	Safe Ear Curette Purple VersaLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 SafeCurett esZF	65445 Q0399
	Safe Ear Currettes	4888	Safe Ear Curette Blue InfantScoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 SafeCurett esZF	65445 Q0399
	Safe Ear Currettes	5777	Safe Ear Curette Variety Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 SafeCurett esZF	65445 Q0399
	Safe Ear Currettes	6333	Safe Ear Curette Yellow CeraSpoon	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 SafeCurett esZF	65445 Q0399



	Safe Ear Curettes	9555	Safe Ear Curette White FlexLoop	remove cerumen and/or foreign	1	5	859911004 SafeCurett esZF	65445 Q0399
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