



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
	Lighted Ear Curette	2210	Lighted Ear Curette AngleLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2220	Lighted Ear Curette MicroLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2230	Lighted Ear Curette Wave	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2240	Lighted Ear Curette FlexLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2250	Lighted Ear Curette CeraSpoon	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2260	Lighted Ear Curette InfantScoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2270	Lighted Ear Curette VersaLoop	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2280	Lighted Ear Curette CeraPik	remove cerumen and/or foreign	1	5	859911004 Lighted CuretteKH	65446 Q0399



				bodies from Ear.				
	Lighted Ear Curette	2245	Lighted Ear Curette Variety Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2201	Lighted Ear Curette AngleLoop Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2202	Lighted Ear Curette MicroLoop Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2203	Lighted Ear Curette Wave Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2204	Lighted Ear Curette FlexLoop Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2205	Lighted Ear Curette CeraSpoon Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2206	Lighted Ear Curette InfantScoop Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2207	Lighted Ear Curette VersaLoop Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Ear Curette	2208	Lighted Ear Curette CeraPik Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399



	Lighted Ear Curette	2209	Lighted Ear Curette Variety Pack Clinic Pack	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399
	Lighted Articulating Ear Curette	2511	Lighted Articulating Ear Curette	remove cerumen and/or foreign bodies from Ear.	1	5	859911004 Lighted CuretteKH	65446 Q0399

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