



## EU DECLARATION OF CONFORMITY

<b>Manufacturer name and address:</b>	Bionix, LLC 1670 Indianwood Circle Maumee, OH 43537 USA
<b>SRN (Single Registration Number):</b>	US-MF-000020408
<b>Authorized Representative name and address (if applicable):</b>	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: <a href="mailto:mail@obelis.net">mail@obelis.net</a>

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 1 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 28/09/21

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
	LightSource	2200	LightSource	Provides illumination for the Lighted Ear Currettes	1	1	859911004 LightSourc eNV	65447  Z129004

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