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 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

Daniel Brooks
2022.04.28
13:12:14 -04'00'

Toledo, OH USA 28/04/22 — Issue place and date

Daniel Brooks — Director of Quality Assurance & Regualtory 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
	Disposable Nasal Speculum	9877	Disposable Speculum 48 ct.	Improve nasal airway field of view.	1	5	859911004 Speculum YH	42449 Q030199
	Disposable Nasal Speculum	9878	Disposable Speculum 20 ct.	Improve nasal airway field of view.	1	5	859911004 Speculum YH	42449 Q030199