



EU DECLARATION OF CONFORMITY

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| 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 |
|---|-----------------------------|--------------------------------|---------------------------------|--|-------|-----------------------------|-----------------------------|-----------------|
| | 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 | 1 | 5 | 859911004 Lighted CuretteKH | 65446 Q0399 |



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|--|---------------------|------|---|--|---|---|-----------------------------|-------------|
| | | | | foreign 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 |



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|--|---|-------------|---|---|----------|----------|--|------------------------|
| | 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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