


## DECLARATION OF CONFORMITY

Manufacturer:	Etymotic Research, Inc 1125 Remington Road   Schaumburg, IL 60173, United States of America																													
Device(s):	ER-20XS High-Fidelity® Earplugs; 																													
Conformity Assessment Route:	<p>Etymotic Research, Inc. uses the following procedures for the CE labeling of this product according to the REGULATION (EU) 2016 425 MDR:</p> <p>EC Declaration of Conformity in compliance with the provisions of the Council Directive 89/686/EEC and with the national standard transposing harmonized standards EN 352-2:2020, and EN 352-7:2020</p> <p>This product is identical to the PPE which is the subject of EC certificate of conformity No. 2777/16976-02/E00-00</p>																													
Variations	<table><tr><th>P/N</th><th>Description</th><th>GUDID/UPC</th></tr><tr><td>20059</td><td>Lucid Hearing Motorsports</td><td>846430005709</td></tr><tr><td>20077</td><td>Lucid Hearing Motorsports LG</td><td>846430005754</td></tr><tr><td>ER20XS -CCC-C</td><td>ER20XS Large Clear Stem/White Tip - Clamshell</td><td>084643001716</td></tr><tr><td>ER20XS -SMF-C</td><td>ER20XS Standard Clear Stem/Frost Tip - Clamshell</td><td>084643001730</td></tr><tr><td>ER20XS -UF-C</td><td>Earplug 1pr Universal Fit in clamshell</td><td>084643002003</td></tr><tr><td>ER20XS -SMF-P</td><td>Earplug 1pr Standard Frost eartip in polybag</td><td>084643001749</td></tr><tr><td>ER20XS -SMFB</td><td>Earplug 1pr Standard Frost eartip (Bulk Pkg)</td><td>846430005808</td></tr><tr><td>ER20XS -CCB</td><td>Earplug 1pr Large Clear eartip (Bulk Pkg)</td><td>846430005815</td></tr></table>	P/N	Description	GUDID/UPC	20059	Lucid Hearing Motorsports	846430005709	20077	Lucid Hearing Motorsports LG	846430005754	ER20XS -CCC-C	ER20XS Large Clear Stem/White Tip - Clamshell	084643001716	ER20XS -SMF-C	ER20XS Standard Clear Stem/Frost Tip - Clamshell	084643001730	ER20XS -UF-C	Earplug 1pr Universal Fit in clamshell	084643002003	ER20XS -SMF-P	Earplug 1pr Standard Frost eartip in polybag	084643001749	ER20XS -SMFB	Earplug 1pr Standard Frost eartip (Bulk Pkg)	846430005808	ER20XS -CCB	Earplug 1pr Large Clear eartip (Bulk Pkg)	846430005815		
P/N	Description	GUDID/UPC																												
20059	Lucid Hearing Motorsports	846430005709																												
20077	Lucid Hearing Motorsports LG	846430005754																												
ER20XS -CCC-C	ER20XS Large Clear Stem/White Tip - Clamshell	084643001716																												
ER20XS -SMF-C	ER20XS Standard Clear Stem/Frost Tip - Clamshell	084643001730																												
ER20XS -UF-C	Earplug 1pr Universal Fit in clamshell	084643002003																												
ER20XS -SMF-P	Earplug 1pr Standard Frost eartip in polybag	084643001749																												
ER20XS -SMFB	Earplug 1pr Standard Frost eartip (Bulk Pkg)	846430005808																												
ER20XS -CCB	Earplug 1pr Large Clear eartip (Bulk Pkg)	846430005815																												

We, the manufacturer, declare that the medical devices specified above meet the provisions of the REGULATION (EU) 2016/425 for medical devices. The declaration is supported by the Quality System approval for the ISO 13485:2016 issued by Intertek Testing Services NA, Inc., Certificate No. 0107044-01

The devices covered by the present declaration are in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. This declaration of conformity is issued under the sole responsibility of Etymotic Research, Inc. All supporting documentation is retained at the premises of the manufacturer.

ISSUED:

X 

Timothy Monroe  
Management Representative

2024-07-24  
Date

SCHAUMBURG IL, USA  
Location