

DECLARATION OF CONFORMITY

<i>Manufacturer:</i>	Etymotic Research, Inc 1125 Remington Road Schaumburg, IL 60173, United States of America
<i>Device(s):</i>	ER-20 High Fidelity Earplugs 

<i>Conformity Assessment Route:</i>	<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. 2777/25817-01/E00-00</p>
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<i>Variations</i>	P/N	Description	GUDID/UPC
	20055	Lucid Hearing Universal	846430005662
	20056	Lucid Hearing Travel	846430005679
	20057	Lucid Hearing Live Events	846430005686
	20058	Lucid Hearing Outdoors	846430005693
	20073	Lucid Hearing Universal LG	846430005716
	20074	Lucid Hearing Travel LG	846430005723
	20075	Lucid Hearing Live Events LG	846430005730
	20076	Lucid Hearing Outdoors LG	846430005747
	ER20-CCC-C	ER20 ETY Plug Large Clear Stem/White Tip - Clamshell	846430000247
	ER20-SMB-C	ER20 ETY Plug Standard Clear Stem/Blue Tip - Clamshell	846430000216
	ER20-SMF-C	ER20 ETY Plug Standard Clear Stem/Frost Tip - Clamshell	846430005624
	ER20-SFT-WHITE	ER-20-Safety-large, white eartip 1pr	846430000322
	ER20-CCB	Earplug 1pr Clear cap LG White tip (Bulk Pkg)	846430005778
	ER20-SMB	Earplug 1pr Clear cap Blue tip (Bulk Pkg)	846430005785
	ER20-SMFB	Earplug 1pr Clear cap Frost tip (Bulk Pkg)	846430005792

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