

DECLARATION OF CONFORMITY

<i>Manufacturer:</i>	Etymotic Research, Inc 1125 Remington Road Schaumburg, IL 60173, United States of America		
<i>Device(s):</i>	ER-20XSD 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. 2777/16976-02/E00-00.</p>		
<i>Variations</i>	P/N	Description	GUDID/UPC
	ER20XSD-UF-C	Earplug – Dual Flange	00846430002401

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