

DECLARATION OF CONFORMITY

ETYMOTIC
RESEARCH^{INC.}

MANUFACTURER: ETYMOTIC RESEARCH, INC.

MANUFACTURER ADDRESS: 61 MARTIN LANE
ELK GROVE VILLAGE ILLINOIS 60007 USA

DEVICE(S): Electronic Level-Dependent Active Hearing Protection
Model: ER125RC-GSE Rechargeable Electronic Earplug



CONFORMITY ASSESSMENT ROUTE: Etymotic Research, Inc. uses the following procedures for the CE labeling of this product according to the REGULATION (EU) 2016/425 MDR:

EC Declaration of Conformity in compliance with the provisions of Council Directive 89/686/EEC and with the national standard transposing harmonized standards EN 352-2:2002, and EN 352-7:2002.

This product is identical to the PPE which is the subject of EC certificate of conformity No. 2777/13059-01/E00-00, issued by Satra 2777, valid through 24/07/2024.

We, the manufacturer, declare that the medical devices specified above meet the provisions of the REGULATION (EU) 2016/425 for medical devices. This declaration is supported by the Quality System approval for ISO 13485:2016 issued by Intertek Testing Services NA, Inc., Certificate No. 0081902.

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:

Steve Iseberg

NAME

January 22, 2024

DATE

Management Representative

TITLE

Elk Grove Village, Illinois USA

LOCATION


SIGNATURE
SIGNATURE