

## Declaration of Conformity

**WE, the manufacturer/supplier declare the battery products identified below**

Brand Name/Trade Marks	DURACELL® zinc air button cell hearing aid batteries
Single Registration Number	BE-MF-000019835
Sizes – Major Cells	10, 13, 312, 675
Basic UDI-DI	5000394HAB01EF

**are herewith confirmed to comply with the requirements set forth in:**

IEC 60086-1	Primary batteries – Part 1: General
IEC 60086-2	Primary batteries – Part 2: Physical & Electrical Specifications
IEC 60086-5	Safety of batteries in aqueous electrolyte

and comply with the marking requirements and substance restriction limits set forth in the **EU Battery Directive 2006/66 and Amendment 2013/56 EU** and contain less than <0.0005% mercury, <0.0020% cadmium, and >0.0040% lead. Therefore, the chemical symbols Hg and Cd are **not** required to be marked below the separate collection symbol. The package is labeled with the trash bin special collection symbol and the “Pb” element symbol.

Subject batteries conform to the requirements of the **EU Medical Regulation 2017/745** class 1 and are marked with the CE symbol.

Batteries are articles under the **EC REACH Regulation (EC 1907/2006)** and are not subject to the REACH registration and SDS requirements. No SVHC substances are present (>0.1% w/w) in accordance with the ECJ article definition of 10 September 2015. This SVHC communication is based on the best available information to us. Duracell is managing compliance with EU REACH as part of our daily quality, safety and regulatory activities. The Candidate List of SVHC’s is updated approximately bi-annually and Duracell will update this declaration accordingly if the updated SVHC list affects the assessment herein.

Batteries are not regulated under the **EU RoHS2 Directive 2011/65/EU and its amendment (EU)2015/863**. Under the EU Battery Directive, the limits for mercury, cadmium and lead are more restrictive than the RoHS limits. Duracell zinc air batteries do not contain any RoHS substances.

BY,



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POSITION : Global Product Safety and Regulatory Affairs – Duracell E&A  
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