



GP Batteries International Limited

Singapore Office

3 Fusionopolis Link #06-10 Nexus @one-north

Singapore 138543

Tel: +65 6559 9800 Fax: +65 6559 9801

Hong Kong Office

7/F, Building 16W, 16 Science Park West Avenue

Hong Kong Science Park, New Territories, Hong Kong

Tel : +852 2484 3111 Fax : +852 2420 3450

Website: www.gpbatteries.com

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer

GP Batteries International Limited

**7/F Building 16W, 16 Science Park West Avenue,
Hong Kong Science Park, New Territories,
Hong Kong**

Authorised Representative

VMB

**VARTA-Platz 1,
73479 Ellwangen
Germany**

We, the manufacturer **GP Batteries International Limited** declare that the Declaration of Conformity is issued under our sole responsibility and belongs to the following product:

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Model: **312**
Product: **Primary Zinc/Air Button Cell (Non-rechargeable)**
Category: **Portable Batteries**
Brand: **GP Batteries**

In accordance with the following Regulation:-
(EU) 2017/745 Medical Devices Regulation

Hereby declare:

Hearing Aid batteries, also known as Zinc Air Hearing Aid Batteries 1.45V
Single registration number (SRN) : DE-MF-000005968
Basic UDI-DI : 40437522464A

Intended purpose : Batteries for hearing aids
Risk class : Class I

The object of the declaration described in above is in conformity with the relevant Union harmonisation legislation:

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

References to the relevant harmonised standards or the common specifications used or references to the other technical specifications in relation to which conformity is declared:

Medical Device Regulation (2017/745):

ISO 13485
ISO 14971
ISO 15223

EU Battery Regulation (2023/1542):

IEC 60086-1
IEC 60086-2

This Declaration of Conformity replaces all previous versions of the above model(s)



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Signed on behalf of GP Batteries International Ltd.

Place of issue: HONG KONG

Date of issue: 7th May 2026

CE

Name and signature of authorised person:

Chris Lee

Function: Senior Supplier Quality Manager