



EU DECLARATION OF CONFORMITY (DoC)

In accordance with Annex IV, Regulation (EU) 2017/745 and Part II of the UK Medical Devices Regulations 2002 (as amended)

We, the manufacturer/distributor;
GP Batteries International Limited
7/F Building 16W, 16 Science Park West Avenue,
Hong Kong Science Park, New Territories,
Hong Kong

In accordance with the following Regulations:-

(EU) 2017/745 Medical Devices Regulation
UKMDR 2002 and Directive 93/42 Medical Device Directive

Hereby declare:
Hearing Aid batteries, also known as Zinc Air Hearing Aid Batteries 1.45V
GMDN Code 46539, EMDN Code Y214580

Family Basic UDI-DI: 5000252HAB21B4
Types (Sizes): 10 (PR70), 312 (PR41), 13 (PR48), 675 (PR44)

Classification assessment is derived from EUMDR 2017/745 Annex VIII Chapter II, 3.2 and Chapter III, 4 – 4.1 Rule 1, UK MDR 2002; Regulation 17, and annex IX of Directive 93/42 and Rule 1.1, and therefore the battery devices are classified as Class 1
The Conformity Assessment Procedure has been performed following Annex II and III of the Regulation (EU) 2017/745 and Annex V11 sec 3 of Directive 93/42.

Intended Use and Purpose Declaration	Size 13	Size 10	Size 312	Size 675
Medical Device Family	Zinc Air Hearing Aid Batteries: 5000252HAB21B4			
Device Name (s)	13 Zinc Air	10 Zinc Air	312 Zinc Air	675 Zinc Air
Typical Designations/References	ANSI : 7000ZD IEC : PR48	ANSI:7005Z IEC:PR70	ANSI:7002Z IEC:PR41	ANSI:7003Z IEC: PR44
Device Identifier	SKU Reference / Barcode on first box packaging level			



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

Intended Use:

The Zinc Air Primary cell basic function is to provide a source of electrical energy by direct conversion of chemical energy; consists of an assembly of electrodes, separators, electrolyte container and terminals.

The Primary use of Zinc Air batteries/cells are for consumer use, to be used within Hearing Aid devices. Four standard battery sizes exist for this type of application.

The Devices are in conformity with Regulation (EU) 2017/745 and UK MDR 2002, Directive 93/42.

The Devices referenced above also comply with IEC 60086-1:2015),2:2015) and 5:2016) (Primary Batteries), (identical to EN 60086-1:2021, EN 60086-2:2021 and EN 60086-5:2021) respectively for General requirements, Physical and electrical specifications, and Safety of batteries with aqueous electrolyte. The Devices also comply with the applicable and effective Articles of Regulation (EU) 2023/1542 and the General Product Safety Directive 2001/95/EC.

Signed on behalf of GP Batteries International Ltd.

Place of issue: HONG KONG

Date of issue: 26th Jun 2024

Name and signature of authorised person:

Chris Lee

Function: Senior Supplier Quality Manager