

## EU Declaration of Conformity under Regulation (EU) 2017/742 (EU MDR)

**Manufacturer:**

AbleNet, Inc.  
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**European Authorized  
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**Notified Body:**

Not applicable.

This declaration of conformity is issued under the sole responsibility of the manufacturer. The device(s) covered by the present declaration are in conformity with all applicable standards and common specifications referenced herein, including compliance with the General Safety and Performance Requirements set out in Annex I of Regulation (EU) 2017/745.

**Product Name / Model:** Buddy Button IC  
**Product Part Number(s):** 10000115  
**Basic UDI-DI:** 00850011150399  
**GMDN Code(s):** 65857— Assistive Electronic Switch  
**EMDN Code(s):** Y210999: Personal computer input and output peripheral equipment – other; Y240999: Control devices and systems – other; Y241899: Arm, hand, finger function aid and/or substitution devices – other; Y214299: Devices for interpersonal communication - other  
**Control Indicator:** Date codes starting 2025W43  
**Intended Purpose:** This switch is used to give access to items that are not normally accessible because of issues with cognitive or motor control.  
**Device Classification:** Class I, based on Annex VIII and Rule 13  
**Conformity Assessment:** Article 52(7) in conjunction with Annex II and Annex III of Regulation (EU) 2017/745 (no notified body involvement for this Class I device).

**Applicable Standards and Common Specifications:**

- BS EN ISO 13485:2016 (Quality Management System).

**Date of Issue:**

20 February 2026

**Place of Issue:**

AbleNet, Inc. – Roseville, MN

**Name:**

Christa Nova

**Title:**

Director, Product Compliance & Risk Management

**Signature:**

Signed by:  
  
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