AbleNet®

# EU Declaration of Conformity

*2625 Patton Road*
*Roseville, MN 55113*
651-294-2200
www.ablenetinc.com

This declaration of conformity is issued under the sole responsibility of the manufacturer. The device covered by the present declaration is in conformity with all regulations below, including compliance with related Essential Requirements.

**Object of the declaration:**

| | |
|---|---|
| **Product Name**: | *Dual Switch Latch & Timer* |
| **Product Model Designator**: | Dual Switch Latch & Timer |
| **Product Part Number(s):** | 100DSLAT |
| **Basic UDI-DI** *<required for MDR>* | *00186648000777* |
| **Control Indicator:** | 2020W20 thru 2025W20 |
| **Global Medical Device Nomenclature Code (GMDN) and Description** | |
| **Product Options/Accessories**: | *N/A* |

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The object of the declaration described above is in conformity with the following regulations:

| **EU Regulation** | **Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices** |
|---|---|
| **Device Classification:** | Class I based on Annex VIII and Rule 13 |
| **Conformity Assessment Path** | *Not Applicable – Class I device* |
| **Name/Address/ID of Notified Body:** | *Not Applicable – Class I device* |
| **Standards and Common Specifications** | The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation and are compliant with the product standards listed below.<br><br>*BS EN ISO 14971:2012 – Medical Devices – Application of risk management to medical devices*<br>*BS EN ISO 13485:2016 – Medical Devices – Quality management systems – Requirements for regulatory purposes* |

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**Additional information:**

| | |
|---|---|
| **EU Authorized Representative**: | *EUCEREP*<br>*Roald Dahllaan 33*<br>*5629MC – Eindhoven*<br>*The Netherlands* |

| | |
|---|---|
| Signature (signed for and on behalf of AbleNet):<br> | Date of Issue: <DD Month YYYY><br>15 April 2021 |
| Printed Name:<br><br>Joe Volp | Place of Issue:<br>AbleNet Inc – Roseville, MN |
| Title:<br>Director of Marketing | Document Number:<br>DoC_100DSLAT_Dual Switch Latch & Timer_041521 |