# Declaration of Conformity for Tempo Smart Button with Statutory Instruments 2002 No. 618, *UK MDR 2002*, 2017 No. 1206, *The Radio Equipment Regulations 2017*, 2012 No. 3032, *The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012*

UK MDR Technical Documentation Number: RPT-393435, Ver 9
UK RED/RoHS Technical Documentation Number: PDS-DHF_DMR-30040, Ver. 5

| Economic Operator | Address |
|---|---|
| Manufacturer | Eli Lilly and Company<br>Pharmaceutical Delivery Systems (PDS)<br>Lilly Corporate Center<br>Indianapolis, IN 46285<br>USA |
| UK Responsible Person | Eli Lilly and Company Limited<br>Lilly House, Basing View<br>Basingstoke, RG21 4FA<br>United Kingdom |

| **Object of Declaration** | **Description** |
|---|---|
| | A Module that attaches to a Tempo Pen and provides insulin dose-related data via Bluetooth to a compatible iOS or Android App that can display insulin dose information. |
| |   |

| **Product Name** | **Item Code** | **UK Risk Class** |
|---|---|---|
| Tempo Smart Button | MS6303 | Class 1<br>(non-measuring/ non-sterile) |

**Intended Purpose:**
The Tempo Smart Button is a device accessory which is intended to collect, store and transfer insulin dose related data from a Tempo Pen to a compatible mobile application (SaMD).

**Methods of Conformity Applied:**

| **Regulation/ Statutory Instrument** | **Method of Conformity** |
|---|---|
| Statutory Instrument 2002 No 618 | Part II, clause 17, Self-Declaration |
| Statutory Instrument 2017 No. 1206 | Schedule 3, Module B, EU-type examination and Module C, Conformity to type-based on internal production control |
| Statutory Instrument 2012 No. 3032 | Schedule 1, Part 4, Internal Production Control |

This UK Declaration of Conformity is issued under the sole responsibility of Eli Lilly and Company, Pharmaceutical Delivery Systems. This declaration was issued in Indianapolis, Indiana, USA.

This Declaration of Conformity covers the Tempo Smart Button as specified in the product list provided on this declaration and is valid for all products concerned bearing the UKCA Marking.

## List of RED Harmonized Standards Applied

| Standard Number (including version) | Description |
|---|---|
| EN 300 328 v2.2.2<br>Date of Issue: July 2019 | Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques |

## List of Other Radio Equipment Standards or Technical Specifications Applied

| Standard Number (including version) | Description |
|---|---|
| EN 301 489-1 v2.2.3 (2019-11) | Electromagnetic Capability (EMC) standard for radio equipment and services part 1: Common technical requirements |
| EN 301 489-17 v3.2.2 (2019-12) | Electromagnetic Capability (EMC) standard for radio equipment and services part 17: Specific conditions for Broadband Data Transmission Systems |
| EN 62368-1:2014 + AC 2015 + A11:2017 | Safety Requirements for Audio/Video, Information and Technology Equipment |
| EN 62479:2010 | Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300GHz) |

## UK Type Examination Certificates:

| Certificate(s) | Issued by | Certificate No. | Issue Date | Expiration Date |
|---|---|---|---|---|
| UK-(Radio Equipment) type Examination Certificate | Element Materials Technology Warwick Ltd. (No. 0891)<br>Unit 1 Pendle Place<br>Skelmesdale, WN8 9PN<br>United Kingdom | EMA21RER0050 | 21Jul2021 | N/A |

## Statement on Description of Accessories:

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|---|---|
| Description of Accessories | The Tempo Smart Button is an accessory to the Mobile Application (SaMD) and will not record or transmit insulin dose related data without being attached to the Tempo Pen. There are no separate accessories or components needed except a Tempo Pen and a Mobile Application (SaMD) to receive transmitted data. The Tempo Smart Button operates in the frequency band between 2.40 and 2.48 GHz. The maximum RF power is -2.40 dBm. The Tempo Smart Button is powered by a non-rechargable, non-replaceable CR1616 (3V) battery |

# Approvals

## Signatures

The required signatures for this Declaration of Conformity are electronically captured within the Electronic Document Management (EDM) system. Electronic signatures are the legally binding equivalent to traditional handwritten signatures.

Electronic approvals, including the dates of approval and the electronic signatures, appear on the cover page of this Declaration of Conformity. The Effective Date also appears on the cover page.

## UK Representative

The undersigned, on behalf of PDS's UK Responsible Person, established in the United Kingdom, declares that the product(s) listed in this Declaration of Conformity is in conformity with Statutory Instruments 2002 No. 618, 2017 No. 1206, and 2012 No. 3032.

| Printed Name | Position Title |
|---|---|
| Cristina Tarancon | Manager Global Regulatory Affairs, EU Labeling |

**Revision History**

| | | |
|---|---|---|
| **Version:** 1 | **Author:** Osman Kafrawy | **Change #:**N/A |
| New Document | | |
| **Version:** 2 | **Author:** Osman Kafrawy | **Change #:** N/A |
| 1. Updated technical documentation revision on page 1<br>2. Updated approver title<br>3. Corrected original version in revision history above. Initial version in Quality Docs is revision 1. | | |
| **Version:** 3 | **Author:** Osman Kafrawy | **Change #:** N/A |
| 1. Corrected description on page 1 of UK Authorized Representative designation with UKRP<br>2. Updated approver | | |
| **Version:** 4 | **Author:** Osman Kafrawy | **Change #:** N/A |
| 1. Updated certificate scope to include compliance with UK MDR 2002 and RoHS<br>2. Added reference to UK MDR Technical Documentation<br>3. Updated Object of Declaration description, Intended Purpose and Description of accessories to clarify module records and transmits insulin dose related data<br>4. Added device classification<br>5. Added methods of conformity applied<br>6. Updated references to radio equipment standards applied to align with conformity assessment certificate (RPT-394569) and DEKRA test reports<br>7. Updated signature meaning for approvers to include all applicable Statutory Instruments<br>8. Updated Regulatory Representative | | |
| **Version:** 5 | **Author**: Osman Kafrawy | **Change#**: 40391578 |
| 1. Revised version ID for EU MDR Technical Documentation RPT-393435<br>2. Clarified UK examination type certificate is specific for radio equipment scope<br>3. Updated UK representative | | |
| **Version**: 6 | **Author:** Everett McKeeman | **Change#**: 40417967, 40414621 |
| 1. Revised version ID for EU MDR Technical Documentation RPT-393435<br>2. Changed header from Document Number to Document Name and version | | |
| **Version**: 7 | **Author:** Everett McKeeman | **Change#**: Doc Only |
| 1. Revised version ID for EU MDR Technical Documentation RPT-393435 | | |
| **Version**: 8 | **Author:** Everett McKeeman | **Change#**: Doc Only |
| 1. Revised version for UK MDR tech doc RPT-393435 and RED tech doc PDS-DHF_DMR-30040 | | |
| **Version**: 9 | **Author:** Everett McKeeman | **Change#**: TR40530556 |
| 1. Revised version for UK MDR tech doc RPT-393435 | | |
| **Version**: 10 | **Author:** Everett McKeeman | **Change#**: TR40439043, TR40300689, TR40437844, TR40574166 |
| 1. Revised version for UK MDR tech doc RPT-393435 | | |

Document Approval Signatures

Approved Date: 23 Apr 2024

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|---|---|
| Approval Task<br>Verdict: Approve | Cristina Tarancon<br>(YS09900@lilly.com)<br>Approver<br>23-Apr-2024 15:44:24 GMT+0000 |
| Reviewer / Approver<br>Additional Details | Appr:<br>Cristina Tarancon - Authorized EU / UK Rep |