Declaration of Conformity for Tempo Smart Button with Regulation (EU) 2017/745, *Medical Device Regulation*, Directive 2014/53/EU, *Radio Equipment Directive* and Directive 2011/65/EU, *Restriction of the use of Certain Hazardous Substances in Electrical and Electronic Equipment*

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

Economic Operator	Address
Manufacturer	Eli Lilly and Company Pharmaceutical Delivery Systems (PDS) Lilly Corporate Center Indianapolis, IN 46285 USA Single Registration Number (SRN): US-MF-000000790, Eli Lilly and Company Pharmaceutical Delivery Systems
EU Authorized Representative	Eli Lilly Nederland B.V. Papendorpseweg 83 3528 BJ UTRECHT The Netherlands Single Registration Number (SRN): NL-AR-000000425, Eli Lilly Nederland B.V.

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**	**Basic UDI-DI**	**EU/UK (NI) Risk Class**
Tempo Smart Button	MS6303	0300020004RM	Class 1 (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/ Directive	**Method of Conformity**
Regulation (EU) 2017/745, Medical Device Regulation	Article 52(7), Conformity Assessment Procedures, Self-Declaration
2014/53/EU, Radio Equipment Directive	Annex III, Module B EU-Type Examination, and Module C, Conformity to type based on internal production control
2011/65/EU, Restriction on the use of certain hazardous substances in electrical and electronic equipment	Annex II, Module A, Internal Production Control

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 CE Marking.

EU Common Specifications (CS) applied: No Common Specifications were applied. CS are not applicable to the product listed above.

List of RED Harmonized Standards Applied

Standard Number (including version)	Description
ETSI EN 300 328 v2.2.2 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

This EU 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.

List of Other Radio Equipment Standards or Technical Specifications Applied

Standard Number (including version)	Description
AIM 7351731	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
EN 301 489-1 v2.2.3 (2019-11)	Electromagnetic Capability (EMC) standard for radio equipment and services part 1: Common technical requirements
(draft) ETSI 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
IEC 62368-1:2014 + AC 2015 + A11:2017	Safety Requirements for Audio/Video, Information and Technology Equipment
EN 62368-1:12014 +AC:2015 +A11:2017	Safety Requirements for Audio/Video, Information and Technology Equipment
UNE EN 62368-1:2014 + A11:2017	Safety Requirements for Audio/Video, Information and Technology Equipment
IEC 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)

EU Type Examination Certificates:

Certificate(s)	Issued by	Certificate No.	Issue Date	Expiration Date
EU-(Radio Equipment) type Examination Certificate	DEKRA Testing and Certification S.A.U. (HQ) (No. 1909) Headquarter Building Parque Tecnológico de Andalucia C/ Severo Ochoa, 2 & 6 29590 Málaga Spain	63324RNB.001	02Dec2020	N/A
		78334RNB.001	12Apr2024	N/A

Statement on Description of Accessories:

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.

EU Representative

The undersigned, on behalf of PDS's Authorized Representative, established in the European Union, declares that the product(s) listed in this Declaration of Conformity is in conformity with Regulation (EU) 2017/745, Directives 2014/53/EU and 2011/65/EU.

Printed Name	Position Title
Cristina Tarancon	Manager, Global Regulatory Affairs, EU Labeling/Product Registration

Revision History

Version: 0	**Author:** Osman Kafrawy	**Change #:**N/A
New Document		
Version: 1	**Author:** Osman Kafrawy	**Change #:**N/A
1. Removed Draft from title based on approval from DEKRA 2. Updated certificate information with certificate number, issue date and expiration date, corrected notified body number 3. Aligned List of Harmonized Standards Applied and List of Other Standards with standards referenced in DEKRA reports		
Version: 2	Author: Osman Kafrawy	Change #: N/A
1. Updated reference to Technical Documentation to list current revision		
Version: 3	**Author:** Osman Kafrawy	**Change #:** N/A
1. Updated technical documentation version on page 1 2. Updated approver title		
Version: 4	**Author:** Osman Kafrawy	**Change #:** N/A
1. Revised to include compliance with Regulation (EU) 2017/745 2. Added reference to Tempo Smart Button EU MDR Technical Documentation 3. Updated Object of Declaration description, Intended Purpose and Description of accessories to clarify module records and transmits insulin dose related data 4. Added Basic UDI-DI and EU MDR Risk Class 5. Added statement for Common Specifications applied 6. Updated EU Representative 7. Updated approval signature meaning to include Regulation (EU) 2017/745		
Version: 5	Author: Osman Kafrawy	Change#: 40391578
1. Revised version ID for EU MDR Technical Documentation RPT-393435 2. Clarified EU Type Examination certificate applies to radio equipment		
Version: 6	**Author:** Everett McKeeman	**Change#**: 40417967, 40414621
1. Revised version ID for EU MDR Technical Documentation RPT-393435 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 EU MDR tech doc RPT-393435 and RED tech doc PDS-DHF_DMR-30040		
Version: 9	**Author:** Everett McKeeman	**Change#**: TR40530556
1. Revised version for EU MDR tech doc RPT-393435		
Version: 10	**Author:** Everett McKeeman	**Change#**: TR40439043, TR40300689, TR40437844, TR40574166
1. Revised version for EU MDR tech doc RPT-393435 2. Added new Dekra certification		

Document Approval Signatures

Approved Date: 23 Apr 2024

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