Title:	EU Declaration of Conformity of Radio Equipment Directive (RED) for Tempo Smart Button

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DRAFT EU Declaration of Conformity for Tempo Smart Button with 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*

Technical Documentation Number: PDS-DHF_DMR-30040, Ver. 0

Radio Equipment **Electrical and Electronic Equipment (EEE)**	Tempo Smart Button	**Item Code**
		MS6303

Manufacturer	**EU Authorized Representative**
Eli Lilly and Company Pharmaceutical Delivery Systems Lilly Corporate Center Indianapolis, IN 46285 USA	Eli Lilly Nederland B.V. Papendorpseweg 83 3528 BJ UTRECHT The Netherlands

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.

Object of Declaration	**Description**	**Item Code**
	A Module that attaches to a Tempo Pen and provides data transmission of a dose administered by the Tempo Pen to a compatible App.	MS6303
		

The object of the declaration described above is in conformity with Directive 2014/53/EU for Radio equipment and 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

This declaration is in accordance with Directive 2014/53/EU, Annex III, Module B, EU-type examination of the Directive, and Module C, Conformity to type based on internal production control.

This declaration is in accordance with Directive 2011/65/EU of the European Parliament per 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.

List of Harmonized Standards Applied

Standard Number (including version)	Description
EN 300 328 v2.2.2 Date of Issue: July 2020	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques

List of Other 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	Electromagnetic Capability (EMC) standard for radio equipment and services part 1: Common technical requirements
(draft) EN 301 489-17 v3.2.2	Electromagnetic Capability (EMC) standard for radio equipment and services part 17: Specific conditions for Broadband Data Transmission Systems
IEC 62368-1-2020+A11	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 Examination Type Certificates:

Certificate(s)	Issued by	Certificate No.	Issue Date	Expiration Date
EU-type Examination Certificate	DEKRA Testing and Certification S.A.U. (HQ) (No. 0344) Headquarter Building Parque Tecnológico de Andalucia C/ Severo Ochoa, 2 & 6 29590 Málaga Spain	TBD	DD-MM-YYYY	DD-MM-YYYY

Statement on Description of Accessories:

Description of Accessories	The Tempo Smart Button is an accessory to the Mobile Application (SaMD) and will not record doses or transmit 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 Directives 2014/53/EU and 2011/65/EU.

Printed Name	Position Title
Janis Bayley	Regulatory Advisor

Regulatory Representative

The undersigned, being the PDS designee for the assessment of the Technical Documentation for the compliance to the requirements of the Radio Equipment Directive, certifies that the Technical Documentation is in conformity with Directives 2014/53/EU and 2011/65/EU.

Printed Name	Position Title
Kevin Bardonner	Sr. Research Scientist - Drug Delivery/Digital Health

DDCS Advisor

The undersigned, being the PDS designee for the assessment of the Technical Documentation for the compliance to the requirements of the Radio Equipment Directive, certifies that the Technical Documentation is in conformity with Directives 2014/53/EU and 2011/65/EU.

Printed Name	Position Title
Cory Henschen	Advisor – DDCS, Delivery and Device Development

PDS Quality Representative

The undersigned, being the PDS designee for the assessment of the Quality System for compliance to the requirements of the Radio Equipment Directive, certifies that the Quality System is in conformity with the 2014/53/EU and 2011/65/EU Directives.

Printed Name	Position Title
Vijay Damodaran	Advisor, IDM Quality PDS Management Representative Person Responsible for Regulatory Compliance

Note: This document will be retained in accordance with the Global Records and Information Management (GRIM) records retention schedule.

Revision History

Version: 0	**Author:** Andre Leriger	**Change #:**N/A
New Document		