Test Report No.: *Prüfbericht-Nr.:*	**US225CE4 001 Rev1.0**	**Order No.:** *Auftrags-Nr.:*	P00755351 234193356	Page 1 of 7 *Seite 1 von 7*
Client Reference No.: *Kunden-Referenz-Nr.:*	2361512	**Order date:** *Auftragsdatum:*	7/6/2022	
Client: *Auftraggeber:*	Otsuka America Pharmaceutical, Inc. 3956 Point Eden Way Hayward, CA 94545 USA			
Test item: *Prüfgegenstand:*	Otsuka Patch			
Identification/ Type No.: *Bezeichnung / Typ-Nr.*	D-Tect			
Order content: *Auftrags-Inhalt:*	RF Exposure Report			
Test specification: *Prüfgrundlage:*	FCC Part 2.1091			
Date of sample receipt: *Wareneingangsdatum:*	10/31/2022	See Test Setup Exhibit for Photos		
Test sample No: *Prüfmuster-Nr.:*	00182, 00196			
Testing period: *Prüfzeitraum:*	10/31/2022- 11/2/2022			
Testing laboratory: *Prüflaboratorium:*	TUV Rheinland of North America 5015 Brandin Ct. Fremont, CA 94538			
Test result*: *Prüfergebnis*:*	Pass			

tested by: *geprüft von:*

Date: 11/15/2022 *Datum:*

Position / Stellung: Expert

authorized by: / *genehmigt von:*

Issue Date: 11/15/2022 *Ausstellungsdatum:*

Position / Stellung: Expert

Others /
Sonstiges:

Condition of the test item at delivery: *Zustand des Prüfgegenstandes bei Anlieferung:* Test sample complete and undamaged

* Legend:	P(ass) = passed a.m. test specification(s)	F(ail) = failed a.m. test specification(s)	N/A = not applicable	N/T = not tested
* *Legende:*	*P(ass) = entspricht o.g. Prüfgrundlage(n)*	*F(ail) = entspricht nicht o.g. Prüfgrundlage(n)*	*N/A = nicht anwendbar*	*N/T = nicht getestet*

Remarks
Anmerkungen

1	The equipment used during the specified testing period was calibrated according to our test laboratory calibration program. The equipment fulfils the requirements included in the relevant standards. The traceability of the test equipment used is ensured by compliance with the regulations of our management system. Detailed information regarding test conditions, equipment and measurement uncertainty is available in the test laboratory and could be provided on request. *Alle eingesetzten Prüfmittel waren zum angegebenen Prüfzeitraum gemäß eines festgelegten Kalibierungsprogramms unseres Prüfhauses kalibriert. Sie entsprechen den in den Prüfprogrammen hinterlegten Anforderungen. Die Rückverfolgbarkeit der eingesetzten Prüfmittel ist durch die Einhaltung der Regelungen unseres Managementsystems gegeben.* *Detaillierte Informationen bezüglich Prüfkonditionen, Prüfequipment und Messunsicherheiten sind im Prüflabor vorhanden und können auf Wunsch bereitgestellt werden.*
2	As contractually agreed, this document has been signed digitally only. TUV Rheinland has not verified and unable to verify which legal or other pertaining requirements are applicable for this document. Such verification is within the responsibility of the user of this document. Upon request by its client, TUV Rheinland can confirm the validity of the digital signature by a separate document. Such request shall be addressed to our Sales department. An environmental fee for such additional service will be charged. *Wie vertraglich vereinbart, wurde dieses Dokument nur digital unterzeichnet. Der TÜV Rheinland hat nicht überprüft, welche rechtlichen oder sonstigen diesbezüglichen Anforderungen für dieses Dokument gelten. Diese Überprüfung liegt in der Verantwortung des Benutzers dieses Dokuments. Auf Verlangen des Kunden kann der TÜV Rheinland die Gültigkeit der digitalen Signatur durch ein gesondertes Dokument bestätigen. Diese Anfrage ist an unseren Vertrieb zu richten. Eine Umweltgebühr für einen solchen zusätzlichen Service wird erhoben.*
3	Test clauses with remark of * are subcontracted to qualified subcontractors and descripted under the respective test clause in the report. Deviations of testing specification(s) or customer requirements are listed in specific test clause in the report. *Prüfklausel mit der Note * wurden an qualifizierte Unterauftragnehmer vergeben und sind unter der jeweiligen Prüfklausel des Berichts beschrieben.* *Abweichungen von Prüfspezifikation(en) oder Kundenanforderungen sind in der jeweiligen Prüfklausel im Bericht aufgeführt.*
4	The test results contained in this report refer exclusively to the product(s) presented for testing. No liability may be assumed for models or products not referred to herein. This test report may not be published or duplicated in part without permission of the testing body. This test report by itself does not constitute authorization for the use of any TÜV Rheinland test mark. The report must not be used by the client to claim product certification, approval, or endorsement by A2LA.
5	Radio Compliance Emissions Test Report. The above product was found to be Compliant to the above test standard(s).

Product description
Produktbeschreibung

1	**Product details:** *Produktdetails:*	The Patch device is a component of the Core Medical Device (CMD) that gathers ingestion, physiological and behavioral metrics from a user.This data is then transmitted to a BLE-enabled gateway device. The data can be accessed by external applications for further processing or displayed directly to a user via a display.
2	**Dimensions / Weight:** *Maße / Gewicht:*	11.3cm x 4.52cm x 0.68cm / 0.011 kg
3	**Operating elements:** *Bedienelemente:*	2.9VDC Battery Operated, Transmit bands 2.402-2.480GHz.
4	**Equipment / Accessories:** *Ausstattung / Zubehör:*	N/A
5	**Used materials:** *Verwendete Materialien:*	None.
6	**Other:** *Sonstiges:*	Test sample(s), as well sample information, description, product details and intended usage was provided by customer.
7	**Test sample obtaining:** *Prüfmusterbereitstellung:*	☒ Sending by customer ☐ Sampling by TÜV Rheinland Group ☐ others:

Revisions

Date mm/dd/yy	Name	Page Number of Change	Describe Change
11/15/2022	Rev. 1	N/A	Original Document

TABLE OF CONTENTS

1 Product Information

1.1 Product Description

The Patch device is a component of the Core Medical Device (CMD) that gathers ingestion, physiological and behavioral metrics from a user. This data is then transmitted to a BLE-enabled gateway device. The data can be accessed by external applications for further processing or displayed directly to a user via a display.

1.2 Product Specifications

The information provided in the following table should be listed as it should appear in the final report.

Table 1 – EUT Specifications*

EUT Specification	
Exposure Type	☒ General Population / Uncontrolled ☐ Occupational / Controlled
DC Power Input	2.9VDC
Environment	Indoor/Outdoor
Operating Temperature Range:	+5 to +40 degrees C
Multiple Feeds:	☐ Yes and how many ☒ No
Product Marketing Name (PMN)	Otsuka Patch
Hardware Version Identification Number (HVIN)	DT3.0
Firmware Version Identification Number (FVIN)	FIRMWARE_VERSION,17,v0.1.4.0 GIT:733
Operating Mode	Bluetooth Low Energy
Transmitter Frequency Band	2402 - 2480 MHz
Power Setting @ Operating Channel	-8 dBm (max)
Antenna Type	Patch
Data Rate	1Mbps and 2Mbps
Antenna Gain (dBi)	-10.1 dBi
Modulation Type	☐ AM ☐ FM ☐ DSSS ☐ OFDM ☒ Other describe: GFSK
TX/RX Chain (s)	1
Note: *All EUT specifications are provided by the manufacturer or the TUV direct customer. Information supplied by the customer and can affect the validity of results.	

2 RF Exposure Test Exemption

2.1 Purpose

In this document, we evaluate the RF Exposure to human body due the intentional transmission from the transmitter (EUT). The limit for RF Exposure Test Exemption specified in FCC 1.1307 is followed.

2.2 RF Exposure Limit

1-mW Test Exemption limit per § 1.1307(b)(3)(i)(A), a single RF source is exempt RF device if the available maximum time-averaged (matched conducted) output power is no more than 1 mW, regardless of separation distance. This exemption applies to all operating configurations and exposure conditions, for the frequency range 100 kHz to 100 GHz, regardless of fixed, mobile, or portable device exposure conditions. This is a standalone exemption, and it cannot be applied in conjunction with any other test exemption.

2.3 Assessment Calculation

The maximum output power and antenna gain is declared by the manufacturer and used in this assessment. The minimum RF exposure distance during normal operation is 5mm.

Stand Alone Analysis ,

Frequency Band (MHz)	Operating Freq (MHz)	Max. Conducted Power (dBm)	Antenna Gain (dBi)	Max. Conducted Power (mW)	Exemption Limit (mW)	Result (Pass/Fail)
2402-2480	2402	-8.21	-10.1	0.151	1	Pass

2.4 Conclusion

The above result had shown that the device complied with RF Exposure test ememption requirement.