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Dear Ms. Lee:

This letter is in response to your request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the PhysiolGuard ECG-QT Analysis System¹ intended to be used by healthcare professionals (HCP) in the hospital setting for remote monitoring and detection of changes in the QT interval of an electrocardiogram (ECG) in general care² patients who are 18 years of age or older (“patients”)³ and are undergoing treatment for Coronavirus Disease 2019 (COVID-19) with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP exposure to SARS-CoV-2, the virus that causes COVID-19.

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.⁴ Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the

¹ The PhysiolGuard ECG-QT Analysis System is comprised of the PhysiolGuard ECG-QT Analysis Platform (an electrocardiogram (ECG) analysis software) and the MiCor A 100 Wearable ECG Recorder. The MiCor A 100 Wearable ECG Recorder is 510(k)-cleared (K162665) for use by users who have transient symptoms that may suggest cardiac conduction abnormalities or by users who want to monitor the cardiac function at home healthcare from Lead 1 ECG signal. PhysiolGuard Corporation Ltd. is the exclusive distributor for the MiCor A 100 Wearable ECG Recorder in the United States. This EUA authorizes the emergency use of the MiCor A 100 Wearable ECG Recorder (that is not 510(k)-cleared for the use described in this EUA) in a system with PhysiolGuard ECG-QT Analysis Platform (that is not FDA approved or cleared). This EUA authorizes use of the PhysiolGuard ECG-QT Analysis System for automated arrhythmia detection of the QT interval of an ECG for patients undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias.

² “General care patients” refer to patients that are not in the intensive care unit (non-ICU).

³ “Patients,” when used in this letter, refer to general care patients that are 18 years of age or older.

⁴ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.⁵

FDA consulted with subject matter experts within HHS on the public health needs for ECG monitoring for complications related to COVID-19 or its treatment (such as QT prolongation). While there are alternative FDA-approved, cleared devices for remote monitoring and detection (e.g., bedside monitors, ECG telemetry units), there are no adequate FDA approved, licensed, or cleared devices for remote patient monitoring and detection of QT interval changes in ECG for patients who are undergoing treatment for COVID-19 with drugs that may cause life-threatening arrhythmias.

Proposed treatments for COVID-19 include the use of drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Common methods to identify those patients rely on monitoring the QT interval of an ECG during drug administration. The QT interval is usually measured on a 12-lead ECG at various timepoints during drug exposures. However, the use of 12-lead ECG recorders on patients that are being treated for COVID-19 is burdensome and may present additional risk to patients and HCPs due to the need for in-person consultations, as well as the need to sanitize the equipment between patients and additional personal protective equipment usage.

Based on bench testing and reported clinical experience, FDA has concluded that the PhysiolGuard ECG-QT Analysis System may be effective for remotely monitoring and detecting the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). In addition, remote monitoring may reduce the HCP risk of exposure to SARS-CoV-2 during the COVID-19 pandemic.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the PhysiolGuard ECG-QT Analysis System, as described in the Scope of Authorization section of this letter (Section II)) and pursuant to the Conditions of Authorization (Section III) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the PhysiolGuard ECG-QT Analysis System, as described in the Scope of Authorization (Section II) of this letter, for remote monitoring and detection of QT interval changes in ECG for patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with

⁵ U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 17335 (March 27, 2020).

azithromycin), meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Physiologuard ECG-QT Analysis System may be effective in remotely monitoring and detecting QT interval changes of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). The known and potential benefits of Physiologuard ECG-QT Analysis System, for such use, outweigh the known and potential risks; and,
3. There is no adequate, approved, and available alternative to the emergency use of the Physiologuard ECG-QT Analysis System for remote monitoring and detection of QT interval changes of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin).⁶

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the Physiologuard ECG-QT Analysis System by HCP in a hospital setting for remote monitoring and detection of changes in the QT interval of an ECG in general care patients who are 18 years of age or older and are undergoing treatment for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP exposure to SARS-CoV-2.

The Physiologuard ECG-QT Analysis System does not provide continuous monitoring of the QT interval of an ECG. The Physiologuard ECG-QT Analysis Platform is not authorized to process ECG data acquired by products other than the MiCor A100 Wearable ECG Recorder. The Physiologuard ECG-QT Analysis System is not intended for use on critical care patients. The Physiologuard ECG-QT Analysis System should not be used during a magnetic resonance imaging (MRI) scan or in a location where it will be exposed to strong electromagnetic forces. The Physiologuard ECG-QT Analysis System is not intended for use as a stand-alone diagnostic monitor for detection of changes in an ECG. The Physiologuard ECG-QT Analysis System is not intended to detect life-threatening abnormal heart rhythms. The Physiologuard ECG-QT Analysis System is not intended to be submerged under more than three (3) feet of water or used in a sauna.

⁶ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

The Authorized Physiologuard ECG-QT Analysis System

The Physiologuard ECG-QT Analysis System, comprised of the Physiologuard ECG-QT Analysis Platform (ECG analysis software) and the MiCor A100 Wearable ECG Recorder, is a wireless remote monitoring system for use by HCPs for collection of ECG data in a hospital setting for remote monitoring and detection of changes in the QT interval of an ECG in general care patients who are 18 years of age or older and are undergoing treatment for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). The Physiologuard ECG-QT Analysis System can be used on one (1) patient for up to fifteen (15) days of ECG monitoring and can then be recharged. To collect an ECG, the user places the ECG electrodes of the MiCor A100 Wearable ECG Recorder against their body for the duration of the recording. The Physiologuard ECG-QT Analysis System employs an automated arrhythmia detection algorithm that can analyze the QT interval of an ECG.

The Physiologuard ECG-QT Analysis System contains the following components:

- The MiCor A100 Wearable ECG Recorder (K162665)
- The Physiologuard ECG-QT Analysis Platform (running on an appropriate cloud server)

The Physiologuard ECG-QT Analysis System also requires the following components:

- Patient smartphone with Android 7 or iOS 12 or above (to transfer data from MiCor A100 Wearable ECG Recorder)
- HCQ.Qtc mobile application running on the patient smartphone to upload ECG recordings to the Physiologuard ECG-QT Analysis Platform
- A computer/smartphone/tablet with internet browser Google Chrome (version 77 or above) to allow HCP to access the Physiologuard ECG-QT Analysis Platform results

The above described Physiologuard ECG-QT Analysis System is authorized to be accompanied with labeling entitled “Physiologuard ECG-QT Analysis Platform User Manual,” “Layuser Instructions to Use MiCor A100 ECG Recorder to Record Lead II and V5 ECG Signals,” and “MiCor A100 Wearable ECG Recorder User Manual” (collectively referred to as the “Instructions for Use,” available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>), together with the following product-specific information pertaining to emergency use, which is required to be made available to HCP and healthcare facilities, respectively:

- Fact Sheet for Healthcare Providers: Physiologuard ECG-QT Analysis System
- Fact Sheet for Patients: Physiologuard ECG-QT Analysis System

The above described product, when accompanied with the Instructions for Use (identified above) and the two Fact Sheets (collectively referred to as “authorized labeling”) is authorized to be distributed under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of PhysiolGuard ECG-QT Analysis System, when used as described in the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized PhysiolGuard ECG-QT Analysis System may be effective in remote monitoring and detection of changes in the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP exposure to SARS-CoV-2, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized PhysiolGuard ECG-QT Analysis System, as described in the Scope of Authorization of this letter (Section II), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized PhysiolGuard ECG-QT Analysis System must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the PhysiolGuard ECG-QT Analysis System described above is authorized for remote monitoring and detection of changes in the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), and such remote monitoring may reduce HCP exposure to SARS-CoV-2.

III. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

PhysiolGuard Corporation Ltd., as Sponsor of Authorized Product

- A. PhysiolGuard Corporation Ltd. must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in Section II of this letter, Scope of Authorization. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

- B. Physiologuard Corporation Ltd. will make the Physiologuard ECG-QT Analysis System available with authorized labeling. Physiologuard Corporation Ltd. may request changes to the authorized labeling. Such changes require review and concurrence from Office of Health Technology 2/ Office of Product Evaluation and Quality/ Center for Devices and Radiological Health (OHT2/OPEQ/CDRH).
- C. Physiologuard Corporation Ltd. may request changes to the Scope of Authorization (Section II in this letter) of the authorized Physiologuard ECG-QT Analysis System. Such requests will be made by Physiologuard Corporation Ltd., in consultation with and require concurrence of OHT2/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).
- D. Physiologuard Corporation Ltd. may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT2/OPEQ/CDRH.
- E. Physiologuard Corporation Ltd. will have process in place for reporting adverse events of which they become aware and will report such events to FDA under 21 CFR Part 803. Physiologuard Corporation Ltd. will establish a process to collect adverse event information from healthcare facility customers.
- F. Physiologuard Corporation Ltd. will notify FDA of any authorized distributor(s)⁷ of the Physiologuard ECG-QT Analysis System, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA and any updates.

Physiologuard Corporation Ltd., and any Authorized Distributor(s)

- G. Physiologuard Corporation Ltd., and authorized distributors will distribute the authorized Physiologuard ECG-QT Analysis System with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the Physiologuard ECG-QT Analysis System according to the criteria set forth by Physiologuard Corporation Ltd.
- H. Physiologuard Corporation Ltd., and authorized distributors will make authorized labeling available on their websites.
- I. Authorized distributors will make Physiologuard Corporation Ltd. aware of any adverse events of which they become aware.
- J. Through a process of inventory control, Physiologuard Corporation Ltd. and authorized distributors will maintain records of the healthcare facilities to which they distribute

⁷ “Authorized Distributor(s)” are identified by Physiologuard Corporation Ltd. in an EUA submission as an entity allowed to distribute the device.

the Physiologuard ECG-QT Analysis System and the number of each product they distribute.

- K. Physiologuard Corporation Ltd. and authorized distributor(s) are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.
- L. Physiologuard Corporation Ltd. and authorized distributor(s) will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Healthcare Facilities

- M. Healthcare facilities using the authorized Physiologuard ECG-QT Analysis System must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet. Healthcare facilities using the authorized Physiologuard ECG-QT Analysis System must also make available the Instructions for Use (authorized labeling) for the Physiologuard ECG-QT Analysis System to patients and HCP.
- N. Healthcare facilities using the Physiologuard ECG-QT Analysis System must make Physiologuard Corporation Ltd. and FDA aware of any adverse events under 21 CFR Part 803.
- O. Healthcare facilities will ensure healthcare providers using the Physiologuard ECG-QT Analysis System are adequately equipped, trained, capable, and will maintain records of device usage.

Conditions Related to Printed Materials, Advertising and Promotion

- P. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized Physiologuard ECG-QT Analysis System shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- Q. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized Physiologuard ECG-QT Analysis System may represent or suggest that this product is safe or effective for remote monitoring of changes in the QT interval of an ECG in patients who are undergoing treatment of COVID-19.
- R. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized Physiologuard ECG-QT Analysis System shall clearly and conspicuously state that:

- The Physiologuard ECG-QT Analysis System has neither been cleared or approved for remote monitoring and detection of changes in the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin);
- The Physiologuard ECG-QT Analysis System has been authorized for the above emergency use by FDA under an EUA;
- The Physiologuard ECG-QT Analysis System has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures