DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715 Industry Information: www.fda.gov/oc/industry	01/13/2025 - 01/17/2025
	FEI NUMBER 3000976525

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Robin Landeck, Global Head of R&D, PCI

FIRM NAME	STREET ADDRESS
Philips Medical Systems Nederland B.V.	High Tech Campus 36
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Eindhoven Noord-Brabant, NL 5656 AE	Medical Device Manufacturer

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The observations noted in this Form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, your firm manufactures the IntelliSpace Cardiovascular (ISCV) software product, an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital cardiovascular images, waveforms and data related to cardiology.

On March of 2023, your firm became aware, through internal testing, of a software defect affecting ISCV Version 7.0 that caused data exports from the ICSV to fail, preventing data from being archived, exported, or copied. Version 7.0 was first installed in the U.S. in April of 2023, after you became aware of the defect. Your firm subsequently received 12 complaints (dated July 2023 – November 2023) from customers reporting issues related to patient studies unable to be archived or transferred, including Complaint #4061517 (dated 13-Nov-2023) alleging that a patient expired due to a delay in transmission of study images possibly resulting in a delay in treatment. Complaint #4061517 states that the "risk was not previously assessed in the RMM [Risk Management Matrix]. The severity of harm has increased from what was predicted in the RMM". Your Correction & Removal Review Board made the decision to (b)(4) dated 31-Jan-2024). Your firm sent notification letters to customers (March 2024) (b)(4) (b)(4) in April 2024. However, this recall was not reported to the FDA with (b)(4)

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	Janet Pulver	Janet Pulver, Medical Device Senior Operations Officer	01/17/2025

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(b)(4) in the Correction and Removal Strategy (b)(4) (dated 25-Mar-2024) as (b)(4) (b)(4) therefore, this is considered not to be a risk to health." Nevertheless, Complaint #4061517 shows that this software defect resulted in the severity of harm to increase from what was predicted in the RMM. Your firm failed to submit a report to the FDA for this recall that was initiated to reduce the risk to health.

OBSERVATION 2

Risk analysis is inadequate.

Specifically,

A. Release of the IntelliSpace Cardiovascular (ISCV) Version 8.0 included a new User Requirement Specification (b)(4) (b)(4) dated 27-Feb-2024) shows the following new requirements were added to the ISCV version 8.0:

(b)(4)

However, your firm failed to include these new product requirements in your ISCV Product Safety Risk (b)(4)

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Management Matrix (Document (b)(4) dated 21-Nov-2024) to ensure that hazards associated with these new functions are analyzed and evaluated, and that appropriate risk control measures are implemented as needed.

B. The Product Safety Risk Management Surveillance Report, Q1 2020, for IntelliSpace Cardiovascular Product Family (dated 05-OCT-2020) documents the results of the quarterly postmarket surveillance performed for the IntelliSpace Cardiovascular (ISCV). The data sources reviewed included the FDA's MAUDE and Recall databases to review experiences with similar or equivalent competitor devices. Records for devices with the same product code as the ISCV (LLZ) were queried. The search identified a Medical Device Report where a hospital reported a patient death due to the system being down and patient images not accessible. Your firm concluded this was not a new hazard because the Risk Management Matrix includes a comparable hazard "Loss of key functionality"; therefore, "no new hazard or hazardous situation". However, your firm failed to consider the increased severity (death) reported in the Medical Device Report. Furthermore, your firm considers for inclusion in the Risk Management Matrix (b)(4) (b)(4) dated 08-Jun-2023).

C. Your firm received 12 complaints (dated July 2023 – November 2023) from customers reporting issues with the IntelliSpace Cardiovascular (ISCV) software product related to patient studies unable to be archived or transferred, including Complaint #4061517 (dated 13-Nov-2023) alleging that a patient expired due to a delay in transmission of study images possibly resulting in a delay in treatment. Your firm concluded this Complaint #4061517 presents a new risk not previously evaluated within the Risk Management Matrix (RMM) and added the risk to the RMM. However, the new hazard (b)(4) (b)(4) (b)(4) because your firm concluded that the ISCV was not the direct cause of the patient's death. Your firm failed to consider the potential for patient serious injury or death, as alleged in Complaint #4061517.

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D. Your IntelliSpace Cardiovascular software product that interfaces with other systems and devices within hospitals' cardiology departments as well as across the enterprise system (e.g., Health Information Systems and Electronic Medical Records). Your firm conducted a security risk analysis to address security and privacy related vulnerabilities of the ISCV, including threat modeling. However, review of the Product Security Risk Management Matrix for the IntelliSpace Cardiovascular 8.0 (dated 17-Apr-2024) showed that the threat modeling conducted was incomplete because it failed to define countermeasures to prevent, mitigate, monitor, or respond to the effects of threats to the ISCV throughout its lifecycle.

OBSERVATION 3

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

A. Review of data downloaded from your (b)(4) shows that >20,000 complaints reporting IntelliSpace Cardiovascular malfunctions (with no deaths or serious injuries reported) were identified as not reportable as Medical Device Reports ("No" entered under "Potentially Reportable Event"); however, there is no valid justification documented to support the decision to not report these malfunctions, including >4,000 (dated Dec 2022 – Nov 2024) reporting "Incorrect, inaccurate, imprecise, or unexpected result" for cardiovascular studies (e.g., Complaints # 5421845, 5358162, 5021318, 4961060, and 2842278), and >2,000 (dated Aug 2023 – Nov 2024) reporting "Data did not transfer / could not be archived" (e.g., Complaints number 5199415, 4999779, 4562214, 4300649, and 3781836).

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B. Review of data downloaded from your complaint handling system showed 436 complaints reporting malfunctions of the IntelliSpace Cardiovascular software product where the cause of the failures was traced to software coding issues. Reportedly these complaints are escalated to your (b)(4) and a ticket is initiated to correct the software (b)(4) Dated April 2022). However, review of the complaint data download shows that 127 out of the 436 complaints with software defects were not escalated to (b)(4) For example:

PR ID	Date Opened	Short Description

(b)(4)

Annotations to Observations 1/17/25 SB

observation 1: Promise to correct

Observation 2: Promise to correct

Observation 3: Promise to correct

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