

# CLARIO.

## SOC 2 REPORT

FOR

### **CLINICAL TRIAL, CARDIAC SAFETY, MEDICAL IMAGING, AND RESPIRATORY SOLUTIONS**

A TYPE 2 INDEPENDENT SERVICE AUDITOR'S REPORT ON  
CONTROLS RELEVANT TO SECURITY AND AVAILABILITY

JANUARY 1, 2023, TO DECEMBER 31, 2023

Attestation and Compliance Services



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# **SECTION I**

## **INDEPENDENT SERVICE AUDITOR'S REPORT**

## INDEPENDENT SERVICE AUDITOR'S REPORT

To Clario:

### Scope

We have examined Clario's accompanying description of its Clinical Trial, Cardiac Safety, Medical Imaging, and Respiratory Solutions system, in Section 3, throughout the period January 1, 2023, to December 31, 2023, (the "description"), based on the criteria for a description of a service organization's system in DC section 200, *2018 Description Criteria for a Description of a Service Organization's System in a SOC 2® Report* (AICPA, *Description Criteria*) ("description criteria"), and the suitability of the design and operating effectiveness of controls stated in the description throughout the period January 1, 2023, to December 31, 2023, to provide reasonable assurance that Clario's service commitments and system requirements were achieved based on the trust services criteria relevant to security and availability ("applicable trust services criteria") set forth in TSP section 100, *Trust Services Criteria for Security, Availability, Processing Integrity, Confidentiality, and Privacy* (AICPA, *Trust Services Criteria*).

Clario uses various subservice organizations for cloud hosting, data center hosting, and off-site tape storage services. The description indicates that complementary subservice organization controls that are suitably designed and operating effectively are necessary, along with controls at Clario, to achieve Clario's service commitments and system requirements based on the applicable trust services criteria. The description presents Clario's controls, the applicable trust services criteria, and the types of complementary subservice organization controls assumed in the design of Clario's controls. The description does not disclose the actual controls at the subservice organizations. Our examination did not include the services provided by the subservice organizations, and we have not evaluated the suitability of the design or operating effectiveness of such complementary subservice organization controls.

The description indicates that complementary user entity controls that are suitably designed and operating effectively are necessary, along with controls at Clario, to achieve Clario's service commitments and system requirements based on the applicable trust services criteria. The description presents Clario's controls, the applicable trust services criteria, and the complementary user entity controls assumed in the design of Clario's controls. Our examination did not include such complementary user entity controls and we have not evaluated the suitability of the design or operating effectiveness of such controls.

### Service Organization's Responsibilities

Clario is responsible for its service commitments and system requirements and for designing, implementing, and operating effective controls within the system to provide reasonable assurance that Clario's service commitments and system requirements were achieved. Clario has provided the accompanying assertion, in Section 2, ("assertion") about the description and the suitability of design and operating effectiveness of controls stated therein. Clario is also responsible for preparing the description and assertion, including the completeness, accuracy, and method of presentation of the description and assertion; providing the services covered by the description; selecting the applicable trust services criteria and stating the related controls in the description; and identifying the risks that threaten the achievement of the service organization's service commitments and system requirements.

### Service Auditor's Responsibilities

Our responsibility is to express an opinion on the description and on the suitability of design and operating effectiveness of controls stated in the description based on our examination. Our examination was conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants (AICPA). Those standards require that we plan and perform our examination to obtain reasonable assurance about whether, in all material respects, the description is presented in accordance with the description criteria and the controls stated therein were suitably designed and operated effectively to provide reasonable assurance that the service organization's service commitments and system requirements were achieved based on the applicable trust services criteria. We believe that the evidence we obtained is sufficient and appropriate to provide a reasonable basis for our opinion.

An examination of the description of a service organization's system and the suitability of the design and operating effectiveness of controls involves the following:

- Obtaining an understanding of the system and the service organization's service commitments and system requirements.
- Assessing the risks that the description is not presented in accordance with the description criteria and that controls were not suitably designed or did not operate effectively.
- Performing procedures to obtain evidence about whether the description is presented in accordance with the description criteria.
- Performing procedures to obtain evidence about whether controls stated in the description were suitably designed to provide reasonable assurance that the service organization achieved its service commitments and system requirements based on the applicable trust services criteria.
- Testing the operating effectiveness of controls stated in the description to provide reasonable assurance that the service organization achieved its service commitments and system requirements based on the applicable trust services criteria.
- Evaluating the overall presentation of the description.

Our examination also included performing such other procedures as we considered necessary in the circumstances.

#### *Service Auditor's Independence*

We are required to be independent and to meet our other ethical responsibilities in accordance with relevant ethical requirements relating to the engagement.

#### *Inherent Limitations*

The description is prepared to meet the common needs of a broad range of report users and may not, therefore, include every aspect of the system that individual users may consider important to meet their informational needs.

There are inherent limitations in the effectiveness of any system of internal control, including the possibility of human error and the circumvention of controls.

Because of their nature, controls may not always operate effectively to provide reasonable assurance that the service organization's service commitments and system requirements are achieved based on the applicable trust services criteria. Also, the projection to the future of any conclusions about the suitability of the design and operating effectiveness of controls is subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

#### *Description of Test of Controls*

The specific controls we tested, and the nature, timing, and results of those tests are presented in Section 4 of our report titled "Testing Matrices."

#### *Opinion*

In our opinion, in all material respects:

- a. the description presents Clario's Clinical Trial, Cardiac Safety, Medical Imaging, and Respiratory Solutions system that was designed and implemented throughout the period January 1, 2023, to December 31, 2023, in accordance with the description criteria;
- b. the controls stated in the description were suitably designed throughout the period January 1, 2023, to December 31, 2023, to provide reasonable assurance that Clario's service commitments and system requirements would be achieved based on the applicable trust services criteria, if its controls operated effectively throughout that period and if the subservice organizations applied the complementary controls assumed in the design of Clario's controls throughout that period; and
- c. the controls stated in the description operated effectively throughout the period January 1, 2023, to December 31, 2023, to provide reasonable assurance that Clario's service commitments and system

requirements were achieved based on the applicable trust services criteria, if complementary subservice organization controls assumed in the design of Clario's controls operated effectively throughout that period.

### *Restricted Use*

This report, including the description of tests of controls and results thereof in Section 4, is intended solely for the information and use of Clario; user entities of Clario's Clinical Trial, Cardiac Safety, Medical Imaging, and Respiratory Solutions system during some or all of the period of January 1, 2023, to December 31, 2023, business partners of Clario subject to risks arising from interactions with the Clinical Trial, Cardiac Safety, Medical Imaging, and Respiratory Solutions system, practitioners providing services to such user entities and business partners, prospective user entities and business partners, and regulators who have sufficient knowledge and understanding of the following:

- the nature of the service provided by the service organization;
- how the service organization's system interacts with user entities, business partners, subservice organizations, and other parties;
- internal control and its limitations;
- complementary subservice organization controls and how those controls interact with the controls at the service organization to achieve the service organization's service commitments and system requirements;
- user entity responsibilities and how they may affect the user entity's ability to effectively use the service organization's services;
- the applicable trust services criteria; and
- the risks that may threaten the achievement of the service organization's service commitments and system requirements, and how controls address those risks.

This report is not intended to be, and should not be, used by anyone other than these specified parties.

*SHELLMAN & COMPANY, LLC*

Washington, District of Columbia  
February 14, 2024