DECLARATION OF CONFORMITY TO 21 CFR PART 11

Title 21 CFR Part 11 of the Code of Federal Regulations deals with the Food and Drug Administration (FDA) guidelines on electronic records and electronic signatures. Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable, and equivalent to paper records (Title 21 CFR Part 11 Section 11.1 (a)). In practical terms, Part 11 requires developers to provide controls, including multiple user logins, user access management, data integrity, electronic signatures and audit trails, for software involved in processing electronic data that are (a) required to be maintained by the FDA predicate rules or (b) used to demonstrate compliance to a predicate rule. A predicate rule is any requirement set forth in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any regulation other than Part 11.

This document declares that the software

Rheocalc T versions 1.1 or later

conforms to the Food and Drug Administration's current thinking regarding the scope and application of Title 21 Part 11 of the Code of Federal Regulations (21 CFR Part 11 (2013)). This declaration applies to the above stated software only when its security controls have been properly configured by the end user. It is the responsibility of the end user to familiarize themselves with the software's security controls, and to configure these controls to meet their company's policies and the applicable regulations. Brookfield's liability under this declaration is limited to that set forth in the current Brookfield Terms and Conditions of Sale.

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