For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

SC-Sanguis Counting
Kontrollblutherstellungs- und Vertriebs GmbH
Im Löchelchen 11
51588 Nümbrecht
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

manufacturing and distribution of in-vitro diagnostic single-use devices and their accessories for the collection, storage and dispensing of blood samples for subsequent in-vitro diagnostic analyses

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from	2025-04-01	Registration No.	D1437900005
Valid until	2028-03-31	Report No.	P24-01569-317931

Stuttgart, 2025-03-19

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00