ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 112329 0001 Rev. 00

Holder of Certificate: **KAMIYA BIOMEDICAL COMPANY, LLC**
12779 Gateway Drive S.
Tukwila, WA 98168
USA

Certification Mark:

Scope of Certificate: **Design and development, distribution, and production of in vitro diagnostic reagents, calibrators and controls for use with clinical chemistry, immunochemistry, and hematology.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 112329 0001 Rev. 00

Report No.: 72175585

Valid from: 2024-02-08
Valid until: 2027-02-07

Date, 2024-02-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

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No. Q5 112329 0001 Rev. 00

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

KAMIYA BIOMEDICAL COMPANY, LLC
12779 Gateway Drive S., Tukwila, WA 98168, USA

Design and development, distribution, and production of in vitro diagnostic reagents, calibrators and controls for use with clinical chemistry, immunochemistry, and hematology.

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