



# Certificate

No. Q5 054291 0012 Rev. 02

**Holder of Certificate:** **Kyokuto Pharmaceutical Industrial Co., Ltd.**  
3333-26, Aza-Asayama, Kamitezuna  
Takahagi-shi, Ibaraki  
318-0004 JAPAN

**Facility(ies):** **Kyokuto Pharmaceutical Industrial Co., Ltd.**  
3333-26, Aza-Asayama, Kamitezuna, Takahagi-shi, Ibaraki,  
318-0004 JAPAN

See scope of certificate

**Certification Mark:**



**Scope of Certificate:** **Design & Development, Production and Distribution of In vitro diagnostic reagents for Clinical Chemistry, Immunology, Genetic Testing and Microbiology, and Cell Culture Media and Culture Media for Clinical Microbiology**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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 054291 0012 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_054291_0012_Rev._02)

**Report No.:** **JN1905882**

**Valid from:** **2022-12-01**  
**Valid until:** **2025-11-30**

**Date,** **2022-12-01**

Christoph Dicks  
Head of Certification/Notified Body