## CERTIFICATE

The Certification Body of TÜV SÜD Management Service GmbH

certifies that

H.U. Group Holdings, Inc.

2-1-1 Nishishinjuku, Shinjuku-ku. Tokyo 163-0408 Japan

has established and applies an Environmental Management System for

Clinical Testings, Research & Development for Clinical Testings. Design, Development, Production of Diagnostic Equipment and Reagent, Production of Raw Material and Bulk Reagent for Immunoassay Device

including the sites see enclosure.

An audit was performed, Order No. 73588736. Proof has been furnished that the requirements according to

**DIN EN ISO 14001:2015** 

are fulfilled.

The certificate is valid from 2022-12-08 until 2025-12-07.

Certificate Registration No.: 12 104 15445 TMS.



Head of Certification Body Munich, 2022-11-24











## **Enclosure of Certificate Registration No.:** 12 104 15445 TMS

Sites	Scope of application
H.U. Group Holdings, Inc. 2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo 163-0408, Japan	Clinical Testings, Research & Development for Clinical Testings.  Design, Development, Production of Diagnostic Equipment and Reagent, Production of Raw Material and Bulk Reagent for Immunoassay Device.
Fujirebio, Inc. Hachioji Facility, Hachioji 2nd Facility, Hachioji 3rd Facility 51 Komiya-machi, Hachioji-shi, Tokyo 192-8535, Japan	Development, Production of Diagnostic Equipment and Reagent
Fujirebio, Inc. Sagamihara Facility 1-3-14 Tanashioda, Chuou-ku, Sagamihara-shi Kanagawa 252-0245, Japan	Production of Diagnostic Reagent
Fujirebio Inc. Tokachi Obihiro Facility 8-36, Nishi-3-sen, Aza-Otofuke, Otofuke-cho, Katou-gun Hokkaido 080-0341, Japan	Production of Raw Material and Bulk Reagent for Immunoassay Device
Fujirebio Inc. Ube Facility 203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi Yamaguchi 759-0134, Japan	Production of Diagnostic Reagent and Raw Material for Immunoassay Device
Fujirebio Inc. Asahikawa Facility 167,1975, 23-chome, Minami 4 jodori, Asahikawa-shi, Hokkaido 078-8334, Japan	Production of Diagnostic Reagent
SRL, Inc. Central Laboratory 50, Fuchigami, Akiruno-shi, Tokyo 197-0833 Japan	Clinical Testings, Research & Development for Clinical Testings







Head of Certification Body Munich, 2022-11-24

Page 2 of 2

