TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.
No. 7, Yan Qi He Xi Yi Rd.
Huairou District
101407 Beijing
China

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture and distribution of in-vitro diagnostic reagents used in the detection of cancer, cardiac markers, endocrine disorders and infectious diseases based on immunological method for clinical laboratory use

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-06-11
Certificate Registration No.:	SX 60135417 0001
An audit was performed. Report No.:	16802804 004
This Certificate is valid until:	2021-10-09

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-06-11

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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