

Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

MedicalSystem Biotechnology Co., Ltd. No. 299, Qiming South Road Yinzhou District 315104 Ningbo

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, Controls and Calibrators using Clinical Chemistry and Rapid Test Technologies

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:

2017-09-21

Certificate Registration No.:

SX 60122891 0001

An audit was performed. Report No.: 15072743 004

This Certificate is valid until:

2020-09-16

Certification Body



Date 2017-09-21



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