

Certificate CN22/00001946

SGS

The management system of

HiComp Microtech (Suzhou) Co., Ltd. HiComp Microtech (Taicang) Co., Ltd.

Room 401, Building 17, Northwest District, Nanopolis Suzhou, No. 99, Jinji Lake Road, Suzhou Industrial Park,
Jiangsu Province, 215123, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Contract Manufacture of Microfluidic Chips (PDMS) used in IVD Reagents and Microfluidic Biochemical Detection Kits
Manufacture of Injection Parts used for IVD Reagents

This certificate is valid from 10 July 2023 until 19 July 2025 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 20 July 2022

Multiple certificates have been issued for this scope, the main certificate is numbered CN22/00001946

Certified activities performed by additional sites are listed on subsequent pages.

Jonathan M. Hall

Authorised by
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ISO 13485:2016
EN ISO 13485:2016

Issue 3
Sites
HiComp Microtech (Suzhou) Co., Ltd. Room 401, Building 17, Northwest District, Nanopolis Suzhou, No. 99, Jinji Lake Road, Suzhou Industrial Park, Jiangsu Province, 215123, P.R. China Contract Manufacture of Microfluidic Chips (PDMS) used in IVD Reagents and Microfluidic Biochemical Detection Kits
HiComp Microtech (Taicang) Co., Ltd. South half of No. 13 Workshop & First floor and second floor, No. 15, Pingqian (Taicang) Modern Industrial Park, No. 525, Yuewang Lingang South Road, Shaxi Town, Taicang City, Suzhou City, Jiangsu Province, P.R. China Manufacture of Injection Parts used for IVD Reagents



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