

EC Certificate



Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2118917-1

Manufacturer: Zhejiang Sorfa Life Science Research
Co., Ltd.
Longshan Road 148#
Zhongguan Town, Deqing County
Huzhou City, 313220
Zhejiang
P.R. China

Products: Aspects of manufacture concerned with securing and maintaining sterile
conditions of Cell Scrapers

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 244320687-200

Effective date: 2021-04-15

Expiry date: 2024-05-26

Issue date: 2021-04-15



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Page 1 of 1

Compliance Report

Applicant: Zhejiang Sorfa Life Science Research Co., Ltd.
 Address: 148 Longshan Road, Zhongguan Town, Deqing 313220, Zhejiang, China.
 Product: Cryogenic Vials, 2D Barcode Cryogenic Vial, Freezing Tube, Plastic Cryogenic Storage Boxes, Color Code, Centrifuge Tubes, Plastic Rack, Cell Strainer, Micro Tube, PCR Tube, Cell Culture Flask, Cell Culture Plate, Cell Culture Dish, Petri Dish, Standard Serological Pipette, Stretching Serological Pipette, Short Serological Pipette, Without Tip Serological Pipette, Aspirating Pipette, Colorized Serological Pipette, Graduated Bacterial Pipette, Cell Culture Pipette, Large Volume Pipette, Pipette Tip, Cell Scraper, Cell Spreaders, Inoculating Loop, Inoculating Needles, Vacuum Filter System, Bottle Top Filter, Solution Bottle, Syringe Filter, Blender bag, Sterile Sampling Bag, Media Bottle, Effervescent Tablet Tubes, Reagent Bottle, Dropper Bottle, FOB Bottle, ESR Pipette, ESR Rack, Diagnostic Cassette, Specimen Container, Transfer Pipette
 Type: See annex for details

Product Classification: Others

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02552

Initial Issue Date: 15 Nov 2016

Tony Chen

General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.

Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
Cryogenic Vials	T101, T102, T114, T115, T131, T132, T133, T134, T135, T136, T137, T138, T139, T2051, T2052, T2053, T2054, T2201, T2202, T2203, T2204
2D Barcode Cryogenic Vial	T2051, T2052, T2053, T2054, T2055, T2016, T2201, T2202, T2203, T2204, T2205, T2206
Freezing Tube	T118, T119, T105, T105-2, T105-3
Plastic Cryogenic Storage Boxes	T130-2, T130-3, T142, T142-1, T142-2, T142-3, T130-1, T145-1, T145-2, T145-3, T145-4, T146, T3051, T3052
Color Code	T144
Centrifuge Tubes	T121-1, T121-2, T121-3, T121-4, T121-5, T121-6, T124-1, T124-2, T124-3, T124-4, T124-5, T124-6, T125-1, T125-2, T125-3, T125-4, T126
Plastic Rack	T127, T128
Cell Strainer	SCS401, SCS701, SCS1001, SCS402, SCS702, SCS1002
Micro Tube	T004-1, T006-1, T008-1, T020-1
PCR Tube	T002-1, T003-1, T016-1
Cell Culture Flask	SCF11050, SCF12050, SCF01050, SCF02050, SCF11250, SCF12250, SCF01250, SCF02250, SCF11600, SCF12600, SCF01600, SCF02600
Cell Culture Plate	SCP11006, SCP01006, SCP10006, SCP00006, SCP11012, SCP01012, SCP10012, SCP00012, SCP11024, SCP01024, SCP10024, SCP00024, SCP11096, SCP01096, SCP10096, SCP00096
Cell Culture Dish	SCD11135, SCD10035, SCD11060, SCD10060, SCD11100, SCD10100, SCD11150, SCD10150
Petri Dish	SPD11035, SPD11060, SPD11100, SPD11101, SPD11061, SPD11150
Standard Serological Pipette	P8010, P8012, P8020, P8022, P8050, P8052, P8100, P8102, P8250, P8252, P8500, P8502, P81000, P81002
Stretching Serological Pipette	P8050-3, P8052-3, P8100-3, P8102-3, P8150-3, P8152-3
Short Serological Pipette	P8010-5, P8012-5, P8020-5, P8022-5, P8050-5, P8052-5, P8100-5, P8102-5, P8250-5, P8252-5

This annex is only valid if attached to the report mentioned above

This report is the property of NQA and should be returned to NQA upon request.

Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
Without Tip Serological Pipette	P8010-4, P8012-4, P8020-4, P8022-4, P8050-4, P8052-4, P8100-4, P8102-4
Aspirating Pipette	P8010-1, P8012-1, P8020-1, P8022-1, P8050-1, P8052-1, P8100-1, P8102-1, P8250-1, P8252-1, P8500-1, P8502-1, P81000-1, P81002-1
Colorized Serological Pipette	P8010-6, P8012-6, P8020-6, P8022-6, P8050-6, P8052-6, P8100-6, P8102-6, P8250-6, P252-6
Graduated Bacterial Pipette	P8310, P8312, P8320, P8322
Cell Culture Pipette	P8410, P8412, P8420, P8422
Large Volume Pipette	PP0020, P0100, P0250, P1000, P2000
Pipette Tip	P900101, P900102, P900103, P900104, P900105, P900106, P900107, P900108, P900109, P900110, P901001, P901002, P901003, P901004, P901005, P902001, P902002, P902003, P902004, P902005, P903001, P903002, P903003, P903004, P903005, P910001, P910002, P910003, P910004, P910005, P912501, P912502, P912503, P912504, P912505
Cell Scraper	SC010, SC011, SC020, SC021
Cell Spreaders	SC110, SC111, SC115, SC116, SC030, SC031, SC040, SC041
Inoculating Loop	L10301S, L10310S, L10401S, L10410S
Inoculating Needles	L10201S, L10210S
Vacuum Filter System	SPE22150, SPE45150, SMC22150, SMC45150, SPV22150, SPV45150, SNY22150, SNY45150, SPE22250, SPE45250, SMC22250, SMC45250, SPV22250, SPV45250, SNY22250, SNY45250, SPE22500, SPE45500, SMC22500, SMC45500, SPV22500, SPV45500, SNY22500, SNY45500, SPE22000, SPE45000, SMC22000, SMC45000, SPV22000, SPV45000, SNY22000, SNY45000

This annex is only valid if attached to the report mentioned above.

Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
Bottle Top Filter	SPE22150S, SPE45150S, SMC22150S, SMC45150S, SPV22150S, SPV45150S, SNY22150S, SNY45150S, SPE22250S, SPE45250S, SMC22250S, SMC45250S, SPV22250S, SPV45250S, SNY22250S, SNY45250S, SPE22500S, SPE45500S, SMC22500S, SMC45500S, SPV22500S, SPV45500S, SNY22500S, SNY45500S, SPE22000S, SPE45000S, SMC22000S, SMC45000S, SPV22000S, SPV45000S, SNY22000S, SNY45000S
Solution Bottle	STF10150, STF10250, STF10500, STF101000
Syringe Filter	SPE22015, SPE45015, SPE22030, SPE45030, SMC22015, SMC45015, SMC22030, SMC45030, SPV22015, SPV45015, SPV22030, SPV45030, SNY22015, SNY45015, SNY22030, SNY45030, SPT22015, SPT45015, SPT22030, SPT45030
Sterile Sampling Bag	SOR1750, SOR1751, SOR1760, SOR1761, SOR1770, SOR1771, SOR1780, SOR1790, SOR1800, SOR1801, SOR1810, SOR1910, SOR1911, SOR1860, SOR1861, SOR1870, SOR1871, SOR1880, SOR1930, SOR1931, SOR1951, SOR1960
Media Bottle	R3150, R3250, R3500, R31000
Effervescent Tablet Tubes	B501, B502, B503
Reagent Bottle	R501, R502, R503, R504, R505, R506, R507, R115, R119, R109-1, R110-1, R116-1, R109-2, R110-2, R116-2, R109-3, R110-3, R116-3
Dropper Bottle	D301-1, D301-2, D301-3, D301-4, D301-5, D302-1, D302-2, D302-3, D302-4, D302-5, D306-1, D306-2, D306-3, D307-1, D307-2, D307-3, D308-1, D308-2, D308-3, D308-4, D308-5, D308-6, D311-1, D311-2, D311-3, D311-4, D311-5, D311-6, D311-7, D311-8, D311-9, D311-10, D311-11, D311-12, D311-13, D311-14, D311-15, D305-1, D305-2, D305-3, D305-4, D305-5, D305-6, D312-1, D312-2, D312-3, D312-4, D312-5, D313-1, D313-2, D313-3, D313-4, D313-5, D315-1, D315-2, D315-3, D315-4, D315-5, D314-1, D314-2, D314-3, D314-4, D314-5, D314-6, D314-7, D314-8

This annex is only valid if attached to the report mentioned above.