



## Zhejiang Sorfa Medical Plastic CO., Ltd

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### To Whom It May Concern:

**Date: 24-April, 2014**

Zhejiang Sorfa Medical Plastic Co., Ltd,  
No.148 Longshan Road, Zhongguan Town, Deqing, Zhejiang, China

Here by certify that

SRL Ecochimie  
Off. 403, 5/1 Cuza Voda bd.  
Chisinau, MD-2060  
Republic of Moldova

Is our authorized exclusive distributor for the entire territory of Moldova to promote and sell the whole range of Sorfa Laboratory Consumable products.

This Certificate is valid until April 23th, 2019.

For An On behalf of Sorfa Medical Plastic.

Yours Sincerely,

**John Jiang**

General Manager



No. 148 Longshan Road, Zhongguan Town, Deqing, Zhejiang, China  
Tel: 86-572-8408068 Fax: 86-572-8408000 Email: info@sorfa.com



## Compliance Report

**Applicant:** Zhejiang Sorfa Life Science Research Co., Ltd.  
**Address:** 148 Longshan Road, Zhongshan 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 Spreader, Inoculating Loop, Inoculating Needles, Vacuum Filter System, Bottle Top Filter, Solution Bottle, Syringe Filter, Blender bag, Sterile Sampling Bag, Media Bottle, Effervescent Filter Tubes, Reagent Bottle, Dyeppor-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.

When 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)



## 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, T100-1, 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	SCP1006, SCP01006, SCP0006, SCP0006, SCP1012, SCP01012, SCP0012, SCP00012, SCP1024, SCP01024, SCP10624, SCP00624, SCP1096, SCP01096, SCP00096, SCP00096
Cell Culture Dish	SCD1135, SCD10035, SCD11060, SCD10060, SCD11100, SCD10100, SCD11150, SCD10150
Petri Dish	SPD11035, SPD11060, SPD11100, SPD11101, SPD11061, SPD11150
Standard	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, P8150-5, P8152-5

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



Annex to Report (No. 02552)

Zhejiang Sorfia Life Science Research Co., Ltd.

Product Name	Type
Without Tip	P8010-4, P8012-4, P8020-4, P8022-4, P8050-4, P8032-4, P8100-4, P8102-4
Serological Pipette	P8010-1, P8012-1, P8020-1, P8022-1, P8050-1, P8032-1, P8100-1, P8102-1, P8250-1, P8252-1, P8500-1, P8502-1, P81000-1, P81002-1
Aspirating Pipette	P8010-6, P8012-6, P8020-6, P8022-6, P8050-6, P8032-6, P8100-6, P8102-6, P8250-6, P8252-6
Colorized	P8310, P8312, P8320, P8322
Serological Pipette	P8410, P8412, P8420, P8422
Graduated	
Bacterial Pipette	
Cell Culture	
Pipette	
Lame Volume	PF0020, P0100, P0250, P1000, P2000
Pipette	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	L1030/S, L10310S, L10401S, L10410S
Inoculating	
Needles	L10201S, L10210S
Vacuum Filter	SPE22150, SPE45150, SMC22150, SMC45150, SPV22150, SPV45150, SNY22150, SNY45150, SPE22250, SPE45250, SMC22250, SMC45250, SPV22250, SPV45250, SNY22500, SNY45500, SMC22500, SMC45500, SPV22500, SPV45500, SNY22500, SNY45500, SPE22000, SPE45000, SMC22000, SMC45000, SPV22000, SPV45000, SNY22000, SNY45000

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Annex to Report (No. 02552)

Zhejiang Sorfia 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
Sterile Sampling Bag	SOR1750, SOR1751, SOR1760, SOR1761, SOR1770, SOR1771, SOR1780, SOR1790, SOR1800, SOR1801, SOR1810, SOR1910, SOR1911, SOR1860, SOR1861, SOR1870, SOR1871, SOR1880, SOR1910, SOR1931, SOR1951, SOR1960
Media Bottle	R3150, R3250, R3500, R31000
Effervescent	B501, B502, B303
Tablet Tubes	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
Reagent Bottle	D301-1, D301-2, D301-3, D301-4, D301-5, D301-6, D301-7, D301-8, D301-9, D301-10, 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, D31-1, D31-2, D31-3, D31-4, D31-5, 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

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Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
FOB Bottle	A101-1, A101-2, A101-3, A101-4, A102-1, A204-1, A205-1, A205-2, A206-1, 206-2, A209-1, A209-2
ESR Pipette	L601, L602, L608, L604
ESR Rack	L610
Diagnostic Cassette	W101, W102, W103, W104, W105, W106, W107, W108
Specimen Container	B301, B302, B303, B304, B305
Blender Bag	SOR2071, SOR2072, SOR2031, SOR2061, SOR2011, SOR2012, SOR2013, SOR2021, SOR2022, SOR2023, SOR2041, SOR2043, SOR2051
Transfer Pipette	P101, P102, P103, P104, P105, P106, P107, P108, P109, P110, P111, P112, P113, P114, P115, P116, P117, P118, P119, P120, P121, P122, P123, P124, P125, P126, P201, P202, P203, P204, P205, P206, P207, P208, P209, P110, P211, P212, P213, P214, P301, P302, P103, P304, P305, P306, P307, P308, P401, P402, P403, P404, P405, P406, P407, P408, P501, P502, P503, P504, P505, P701, P702, P703, P704, P705, P706, P602, P604, P605, C101, C102, C103, E101, E102, E105, E104

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# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

**Manufacture and Distribution of Disposable Labwares and  
Instruments in Medical Use, Cell Scrapers**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012  
EN ISO 13485:2012/AC:2012**

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

Effective Date: 2016-02-06  
Certificate Registration No.: SX 60107766 0001  
An audit was performed. Report No.: 15091959 001  
This Certificate is valid until: 2019-02-05

Certification Body



Date 2016-02-06



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel. +49 221 866-1371 Fax. +49 221 866-9955 e-mail:cert-validity@de.tuv.com http://www.tuv.com/rs/ley



**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60107765 0001

**Report No.:** 15091959 001

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

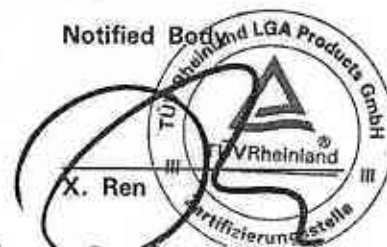
**Products:** Aspects of manufacture concerned with securing and  
maintaining sterile conditions of Cell Scrapers  
  
Replaces Approval, Registration No.: DD 60041680 0001

**Expiry Date:** 2021-02-05

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.

**Effective Date:** 2016-02-06

**Date:** 2016-02-06



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

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

