



Zhejiang Sorfa Medical Plastic CO., Ltd

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

nqa.

Compliance Report

Applicant:
Address:

Zhejiang Sorfa Life Science Research Co., Ltd.
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
Spreader, Inoculating Loop, Inoculating Needles, Vacuum Filter
System, Bottle Top Filter, Solution Bottle, Syringe Filter, Blender
bag, Sterile Sampling Bag, Media Bottle, Effluents Tubes,
Reagent Bottle, Dryer Bottle, FOB Bottle, ESR Pipette, ESR
Rack, Diagnostic Cassette, Specimen Container, Transfer Pipette
See annex for details

Type:

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 affixes 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

General Manager (Signature)

Tong Chen

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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, SCP10006, SCP10102, 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	P8010, P8012, P8020, P8022, P8050, P8052, P8100, P8102, P8250, P8252, P8500, P8502, P81000, P81002
Serological Pipette	P8050-3, P8052-3, P8100-1, P8102-3, P8150-3, P8152-3
Stretching Serological Pipette	P8010-5, P8012-5, P8020-5, P8022-5, P8050-5, P8052-5, P8100-5, P8102-5, P8250-5, P8252-5
Short Serological Pipette	

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

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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	P8010-6, P8012-6, P8020-6, P8022-6, P8050-6, P8052-6, P8100-6, P8102-6, P8250-6, P8252-6
Graduated Bacterial Pipette	P8310, P8512, P8320, P8322
Cell Culture Pipette	P8410, P8412, P8420, P8422
Large Volume Pipette	P90020, 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, SC010, SC011, SC020, SC021
Cell Scraper	SC100, SC111, SC115, SC116, SC030, SC031, SC040, SC041
Cell Spreaders	L10301S, L10310S, L10401S, L10410S
Inoculating Loop	L10201S, L10210S
Inoculating Needles	SPE22150, SPE45150, SMC22150, SMC45150, SPV22150, SPV45150, SNY22150, SNY45150, SPE22250, SPE45250, SMC22250, SMC45250, SPV22250, SPV45250, SNY22250, SNY45250, SPE45500, SMC22500, SMC45500, SPV22500, SPV45500, SNY22500, SNY45500, SPE22000, SPE45000, SPV45000, SMC22000, SMC45000, SPV22000, SPV45000, SNY22000, SNY45000
Vacuum Filter System	

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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, SPE22800S, SPE45000S, SMC22800S, SMC45000S, SPV22800S, SPV45000S, SNY22800S, SNY45000S
Solution Bottle	STF10150, STF10250, STF10500, STF101000 SPE22015, SPE45015, SPE22030, SPE45030, SMC22815, SMC45015, SMC22830, SMC45030, SPV22015, SPV45015, SPV22030, SPV45030, SNY22015, SNY45015, SNY22030, SNY45030, STF22015, STF45015, STF22030, STF45030
Syringe Filter	SOR1750, SOR3751, SOR1760, SOR1761, SOR1770, SOR1771, SOR1780, SOR3790, SOR1800, SOR201, SOR1810, SOR1910, SOR1911, SOR1860, SOR1861, SOR1870, SOR1871, SOR1880, SOR1930, SOR1931, SOR1951, SOR1960
Sterile Sampling Bag	R3150, R3250, R3500, R31000
Media Bottle	B301, B302, B303
Fluorescent	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
Tablet Tubes	D301-1, D301-2, D301-3, D301-4, D301-5, D302-1, D302-2, D302-3, D302-4, D302-5, D306-1, D306-2, 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
Reagent Bottle	
Dropper Bottle	

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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, A206-2, A209-1, A209-2
ESR Pipette	L601, L602, 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, P210, P211, P212, P213, P214, P301, P302, P303, 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, E103, 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 60107786 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. +49 221 806-1371 Fax. +49 221 806-3935 e-mail:cert-validity@de.tuv.com <http://www.tuv.com/az/de>

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

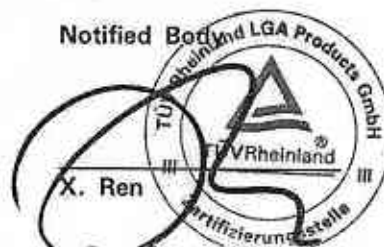
Expiry Date: 2021-02-05

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

Notified Body



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.

