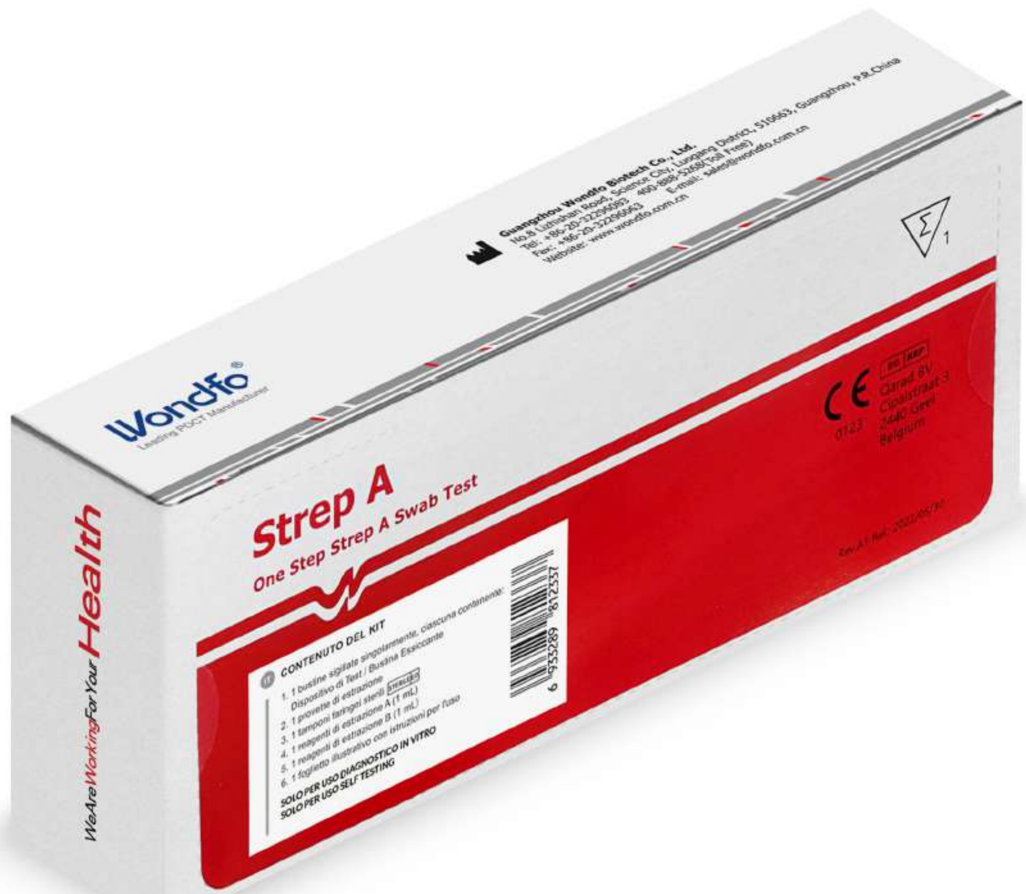

Wondfo
Leading POCT Manufacturer
Guangzhou Wondfo Biotech Co., Ltd.
Website: www.wondfo.com.cn
Strep A
One Step Strep A Swab Test
CONTENUTO DEL KIT
1. 1 bustine sigillate singolarmente, ciascuna contenente:
Dispositivo di Test / Bustina Essiccante
1 provette di estrazione
2. 1 tamponi faringei sterili
3. 1 reagenti di estrazione A (1 mL)
4. 1 reagenti di estrazione B (1 mL)
5. 1 foglietto illustrativo con istruzioni per l'uso
SOLO PER USO DIAGNOSTICO IN VITRO
SOLO PER USO SELF TESTING
6 933289 812337
0123
Qarad BV
Cipalstraat 3
2440 Geel
Belgium
WeAreWorkingForYourHealth

Guangzhou Wondfo Biotech Co., Ltd

EC DECLARATION OF CONFORMITY

According the In Vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer:	Guangzhou Wondfo Biotech Co., Ltd.
Address:	No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
In vitro diagnostic device(s):	**Product Name:** Strep A One Strep A Swab Test

This declaration of conformity is issued under the sole responsibility of the manufacturer that that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

EC Representative: Qarad BV, Cipalstraat 3, 2440 Geel, Belgium

The following (harmonized) standards have been applied:

EN ISO 13485:2012	EN ISO 18113-1:2011	EN ISO 14971:2012
EN ISO 18113-2:2011	EN ISO 15197:2015	EN ISO 15223-1:2016
EN ISO 23640:2015	EN 62366:2008	EN ISO 17511:2003
EN 13612:2002		

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **98/79 EC Annex III**

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentations are retained under the premises of the manufacturer. Guangzhou Wondfo Biotech Co., Ltd is exclusively responsible for the declaration of conformity.

GuangZhou, Jan. 17. 2021	Yaqin Chi, Vice-President of Regulatory Affairs Yaqin Chi
(Place and date of issue)	(name and signature or equivalent marking of authorized person)

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **1798068**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Normativa:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:21/01/2023

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIO
Dispositivo	1798068	S	W39-CH	ONE STEP STREP A SWAB TEST	W0105090103 - STREPTOCOCCUS PYOGENES (GRUPPO A) - TEST RAPIDI E "POINT OF CARE"	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	15/03/2019		FABBRICANTE	GUANGZHOU WONDFO BIOTECH CO. LTD			CN
										MANDATARIO	QARAD BVBA		0471972009	BE

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:1

Indietro

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6) (List A and B and devices for self-testing)

No. V1 18 01 58008 024

Manufacturer:

GUANGZHOU WONDFO BIOTECH CO., LTD.

No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Qarad b.v.b.a

Cipalstraat 3
B-2440 GEEL
BELGIUM

Product Category(ies):

Products for determination of tumor markers (PSA)
Chlamydia, Blood Glucose and self testing products

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH18141EXT01

Valid from: 2018-04-09
Valid until: 2023-04-08

Date, 2018-02-01

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 18 01 58008 024

Model(s):

One Step Prostate Specific Antigen (PSA) Serum/Plasma Test,
One Step Prostate Specific Antigen (PSA) Whole Blood/Serum/Plasma Test,
One Step FSH Urine Test,
Blood Glucose Monitoring System for Self Testing,
One Step Strep A Swab Test,
One Step Chlamydia Swab Test,
One Step Influenza A Test,
One Step Influenza B Test,
One Step Influenza A&B Test,
Digital Pregnancy Test,
PSA Rapid Quantitative Test,
Sperm Concentration Test,
One Step Fecal Occult Blood (FOB) Test
Prostate Specific Antigen Control,
Diagnostic kit for Human IgM Antibody of Chlamydia Pneumoniae(Immunochromatographic Assay),
Digital OvulationTest,
FPSA (Free Prostate Specific Antigen) Quantitative Rapid Test,
Digital Pregnancy Test with Conception Indicator

Facility(ies):

GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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