TÜVRheinland®

CE Technical Documentation Review Report

Manufacturer:	**Chengdu Seamaty Technology Co., Ltd.** No.1 Floor 1 Building1, No.1 Floor 1 Building2, No.333 Hezuo Road, Hi-Tech Zone of Chengdu, Sichuan 611731, P.R. China
Report Number:	15096758 001
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	Auto Dry Biochemistry Analyzer
Type(s)/Model(s):	SD1, SD1-E, SD1-S, SD1-B, SD1-ES, SD1-EB, SD1-BS
Classification:	IVD products other than those covered by Annex II and devices for performance evaluation (according to manufacturer's declaration)
Review result:	During the examination of the provided Technical Documentation (No.: SMT-GL-42, Revision.A0, Date 2019-09-24) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

TÜV Rheinland (Shanghai) Co., Ltd.

Products Quality Assurance TÜVRheinland® Approved

Shanghai, 2019-11-18

Andereas Fu
Lead Auditor, Product Assessor
Medical Services

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EC Declaration of Conformity

Manufacturer: Chengdu Seamaty Technology Co.,Ltd
Address : No.1 Floor 1 Building1, No.1 Floor 1 Building2, No.333 Hezuo Road, Hi-Tech Zone of Cheng du, Sichuan 611731, P.R. China
European Authorized Representative: MedNet GmbH
Address : Borkstrasse 10, 48163 Münster, Germany, DIMDI No. DE/0000012115.
We, the manufacturer, herewith declare that the products

Product Name: Auto Dry Biochemistry Analyzer

Model Number: SD1、SD1-E、SD1-S、SD1-B、SD1-ES、SD1-EB、SD1-BS
Classification: Other IVD devices
General applicable directives:
EN61010-1:2010、EN 61010-2-081:2015、EN 61010-2-101:2017、IEC 61010-2-101:2015 for use in conjunction with IEC 61010-1:2010; EN 61326-1: 2013 ,Class A、EN 61326-2-6: 2013; IEC 62471:2006/EN62471:2008; ASTM D4169:2016 DC3-schedule A-Level Ⅱ; EN ISO 13485: 2016

meet the provisions of Directive 98/79/EC which apply to them.
The medical device has been assigned to In Vitro Diagnostic Medical Devices other than those covered by annex II and devices for performance evaluation according to the Directive 98/79/EC.
It bears the mark

CE

TÜVRheinland® CERTIFIED
Management System EN ISO 13485:2016
www.tuv.com ID 0000051350

The product concerned has been manufactured following the procedure relating to the EC Declaration of Conformity set out in **Annex III** of Directive 98/79/EC.
This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
The above mentioned declaration of conformity is exclusively under the responsibility of
Company: TÜV Rheinland (Shanghai) Co., Ltd.
Address: TÜV Building I, No.177, Lane 777, West Guangzhong Road Zhabei District, Shanghai, China
NB Identification number: 0197
Certificate of quality management system number: SX 60127420 0001
Check the test report number : 50219160 001 , 50232753 001, 50198690 001 , 50058051/SHF/01-03
CE Technical Documentation Rrview Report number: 15096758 001
SMT-GL-42 Rev:A0 ,Date:2019-9-24
Start of CE Marking: 2019-12-01

Chengdu, Sichuan, China, 2019-11-20 — Peng Ran (Gencral Manager)
Place , date — *Legally binding signature, Function*