EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: *HANGZHOU REALY TECH CO., LTD.*
Address:4th Floor,#12 Building,Eastern Medicine Town,Xiasha Economic&Technology Development,310018 Hangzhou,Zhejiang,P.R.China

Product/s	*Catalogue number*
Novel Coronavirus（SARS-Cov-2）Antigen Rapid Test Cassette（swab）	K511416D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III,except Point 6,of Directive

Applicable Standards:EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;EN ISO 17511:2003; EN ISO 18113-1:2011;EN ISO 18113-2:2011,EN ISO 23640:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH,located at Kochstr.1,47877, Willich,Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou 2020.8.17

(Place and date of issue)

Dean

(Signature and position)

Signed for and on behalf of the manufacturer

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157558

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **09.09.2020**		Registriernummer / Registration number **DE/CA20/01-IVD-Luxuslebenswelt-210/20**
	Typ der Anzeige / Notification type Erstanzeige / Initial notification Änderungsanzeige / Notification of change Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG Hersteller / Manufacturer Bevollmächtigter / Authorised Representative Einführer / Importer Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000047791**		
	Bezeichnung / Name **Luxus Lebenswelt GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hangzhou Realy Tech Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Hangzhou**		Postleitzahl / Postal code **310018**
	Straße, Haus-Nr. / Street, house no. **4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic &Technology Development**		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Lin Sun**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	Erstanzeige / Initial notification Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification Produkt der Liste A, Anhang II / Device of List A, Annex II Produkt der Liste B, Anhang II / Device of List B, Annex II Produkt zur Eigenanwendung / Device for self-testing Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) ja / yes nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)**
	Produktbezeichnung / Name of device **Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)**
	Angabe der benutzten Nomenklatur / Nomenclature used EDMS-Klassifikation / EDMS Classification GMDN
	Nomenklaturcode / Nomenclature code **15-70-90-90-00**
	Nomenklaturbezeichnung / Nomenclature term **OTHER OTHER VIROLOGY RAPID TESTS**
	Kurzbeschreibung / Short description In Deutsch / In German **Das COVID-19 Ag-Schnelltestgerät ist ein diagnostischer In-vitro-Test zum qualitativen Nachweis neuartiger Coronavirus-Antigene in Nasentupfer- und Nasenaspiratproben unter Verwendung der schnellen immunochromatographischen Methode. Die Identifizierung basiert auf den monoklonalen Antikörpern, die für das neue Coronvirus-Antigen spezifisch sind. Es wird Informationen für klinische Ärzte bereitstellen, um korrekte Medikamente zu verschreiben.**
	In Englisch / In English **The COVID-19 Ag Rapid Test Device is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in Nasal Swab and nasal aspirate samples, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronvirus antigen. It will provide information for clinical doctors to prescribe correct medications.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Willich**

Datum
Date **2020-08-13**

Name
Lin Sun

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Nadine Schlingmeier**		Telefon / Phone **0211-475-3853**

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **HANGZHOU REALY TECH CO., LTD.**
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: **1990347**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:06/09/2020

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	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	1990347	S	K511416D	NOVEL CORONAVIRUS (SARS-COV-2) AGTEST RAPIDO CARD	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	04/09/2020		FABBRICANTE	HANGZHOU REALY TECH CO., LTD.			CN
									MANDATARIO	LUXUS LEBENSWELT GMBH		DE305829099	DE

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

海 运
By Sea

NO.2020088765

CNAS 中国认可 检验 INSPECTION CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒抗原检测试剂盒

Sample Name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)

委托单位： 杭州睿丽科技有限公司

生产单位： 杭州睿丽科技有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

海 运
By Sea

海 运
By Sea

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020088765

样品名称 Sample Name	中文 Chinese	新型冠状病毒抗原检测试剂盒
	英文 English	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)
委托单位 Consignor		杭州睿丽科技有限公司
生产单位 Manufacturer		杭州睿丽科技有限公司
检验方法、程序 Inspection Methods and Procedures		国际海事组织《国际海运危险货物规则》(2018版) IMO International Maritime Dangerous Goods Code (2018 Edition)
样品外观与气味 Appearance & Odor		多种颜色纸盒(内含白色塑料测试板及无色透明液体)，稍有气味 Multicolor Paper box(containing white plastic test board and colorless transparent liquid), Weak odor

IDENTIFICATION CONCLUSION 鉴定结论

1. 危险性识别(Hazards identification)

无。
None.

2. 海运按照IMO IMDG Code办理的类项(Suggestion according to IMO IMDG Code)

根据特殊规定286，可按非限制性货物条件办理。
The substance is not subject to IMO IMDG Code according to special provision 286.

3. 包装要求(Packaging requirements)

无。
None.

检验日期: Inspection Date: 2020-08-31　签发日期: Issue Date: 2020-08-31　生效日期: Effective Date: 2020-08-31

备注 Comment	无。 None.

批准 Approver: 张小欧　审核 Checker: 钱玉娟　主检 Appraiser: 周敏

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020088765

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:752693-

报告结束

空 运
By Air

NO.2020088764

中国认可
检验
INSPECTION
CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒抗原检测试剂盒

Sample Name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)

委托单位： 杭州睿丽科技有限公司

生产单位： 杭州睿丽科技有限公司

上海化工院检测有限公司
检验检测专用章

上化院 上海化工院检测有限公司
Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空 运
By Air

空 运
By Air

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020088764

样品名称 Sample Name	中文 Chinese	新型冠状病毒抗原检测试剂盒
	英文 English	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)
委托单位 Consignor		杭州睿丽科技有限公司
生产单位 Manufacturer		杭州睿丽科技有限公司
检验方法、程序 Inspection Methods and Procedures		国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition
样品外观与气味 Appearance & Odor		多种颜色纸盒(内含白色塑料测试板及无色透明液体)，稍有气味 Multicolor Paper box(containing white plastic test board and colorless transparent liquid),Weak odor

IDENTIFICATION CONCLUSION 鉴定结论

1. 危险性识别(Hazards identification)

无。
None.

2. 空运按照IATA DGR办理的类项(Suggestion according to IATA DGR)

根据特殊规定A122，可按非限制性货物条件办理。
The substance is not subject to IATA DGR according to special provision A122.

3. 包装要求(Packaging requirements)

无。
None.

检验日期: Inspection Date: 2020-08-31　签发日期: Issue Date: 2020-08-31　生效日期: Effective Date: 2020-08-31

备注 Comment	无。 None.

批准 Approver: 张小帆　审核 Checker: 钱玉鹏　主检 Appraiser: 周敏

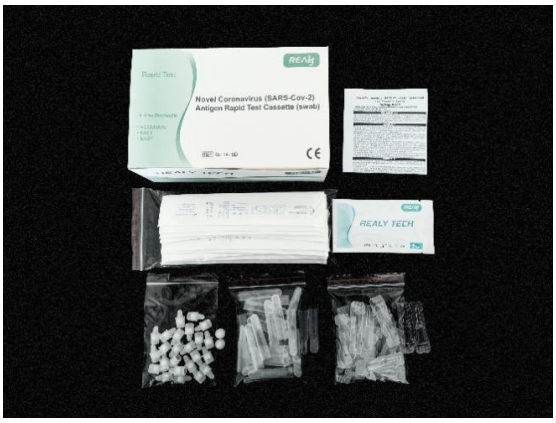
货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020088764

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:220172-

报告结束



25 tests/kit

500 tests/carton

Carton size: 45*44*28cm

Volume: 0.056CBM

Gross weight per carton: 7.5KG

Volume weight per carton via air cargo:9.5KG

Volume weight per carton via express:11.5KG

5 tests/kit

1075 tests/carton

Carton size: 65*55*45cm

Volume: 0.16CBM

Gross weight per carton: 20KG

Volume weight per carton via air cargo: 27KG

Volume weight per carton via express: 32KG