Calth | AllCheck Covid-19 Ag

One Step Rapid Test

Certification

b-to-b

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Certificate of
Ministry of Food and Drug Safety

인정번호(No.) :KTL-AABA-6670

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)

(주)켈스

CALTH(Care Health)

■ 대표자 (Representative)

이동호 (Lee Dong Ho)

■ 업체 소재지 (Company address of Applicant)

경기도 안양시 동안구 벌말로 140 , 7508호, 7507-1호(관양동, 동일테크노타워7차)

7508 & 7507-1, 140, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14057, Republic of Korea

■ 제조소명 (Name of Manufacturer)

제조자 : (주)켈스(CALTH(Care Health))

■ 제조소 소재지 (Address of Manufacturer)

제조자 : (본사) 경기도 성남시 창업로54, 321호(시흥시, 기업성장센터), (공장) 경기도 안양시 동안구 벌말로 140, 7508호, 7507-1호(관양동, 동일테크노타워7차)

(Head office) 321, 54, Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, 13449, Republic of Korea, (Manufacturing site) 7508 & 7507-1, 140, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14057, Republic of Korea

■ 품목군 (Category)

체외진단 의료기기용 시약류(Reagent for In-Vitro Diagnostic Device)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2019. 10. 10

유효기간(Date of Expiration) : 2022. 10. 09

경인지방식품의약품안전청장
GYEONGIN REGIONAL FOOD AND DRUG ADMINISTRATION

한 국 산 업 기 술 시 험 원 장
Korea Testing Laboratory

Certificate of Free Sales

Document Number : YZU9-WSTB-IOBV-TY0P

Ministry of Food and Drug Safety

Osong Health Technology Administration Complex, 187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu, Cheongju-si, Chungcheongbuk-do, Korea, 28159 Tel: +82-43-719-5375, Fax: +82-43-719-5350

Certificate of Free Sales

No. of Certificate : 20200126407
Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following product(s) is(are) permitted to be freely sold in overseas market only.

○ Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)

- Name : CALTH Inc.

- Address : 7508 & 7507-1, 140, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14057, Republic of Korea

- Registered No : Manufacturer IVD-4753

No. and date of product-license, comments	Classification
IVD-20-875 / OCT. 12. 2020	IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), immunological method [3] Name of Product : AllCheck COVID19 Ag

※ Attached, if necessary (approved product information)
■ Model(Export Name) ☐ Medical Device Accessaries ☐ Manufacturer/Legal manufacturer
☐ Combined/Composite medical device

Issued date : OCT. 14. 2020 (Certificate No.20200126407)

Certified by 정 현 철

Director
Director for Novel Products Approval
Ministry of Food and Drug Safety

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

Certificate of Free Sales

Document Number : YZU9-WSTB-IOBV-TY0P

Attachment

Product License No. : IVD-20-875 (OCT. 12. 2020)

Classification : IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), immunological method

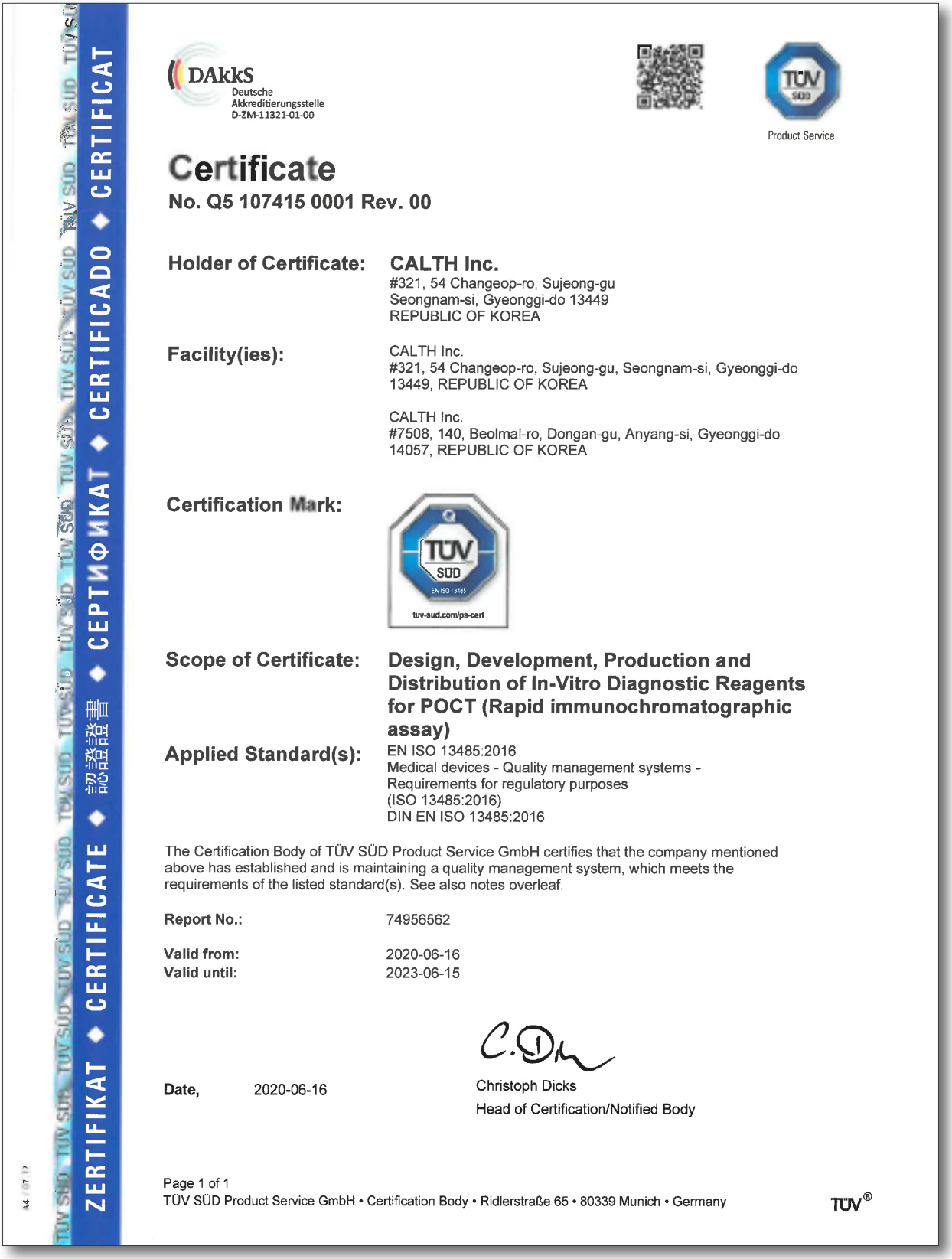
Model(Export Name)

· CHR11

식품의약품안전처

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

Certificate for
In Vitro Diagnostic Medical Device



DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 107415 0001 Rev. 00

Holder of Certificate: **CALTH Inc.**
#321, 54 Changeop-ro, Sujeong-gu
Seongnam-si, Gyeonggi-do 13449
REPUBLIC OF KOREA

Facility(ies):
CALTH Inc.
#321, 54 Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do
13449, REPUBLIC OF KOREA

CALTH Inc.
#7508, 140, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do
14057, REPUBLIC OF KOREA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of In-Vitro Diagnostic Reagents for POCT (Rapid immunochromatographic assay)**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74956562

Valid from: 2020-06-16
Valid until: 2023-06-15

Date, 2020-06-16

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

Certificate of EU Product Notification

www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULTING

Certificate
of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

CALTH Inc.
#321, 54 Changeop-ro, Sujeong-gu, Seongnam-si
Gyeonggi-do, 13449
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).

The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

4 November 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

Certificate of
EU Product Notification

www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULTING

CALTH Inc.

Annex I

to "Certificate of EU Product Notification"

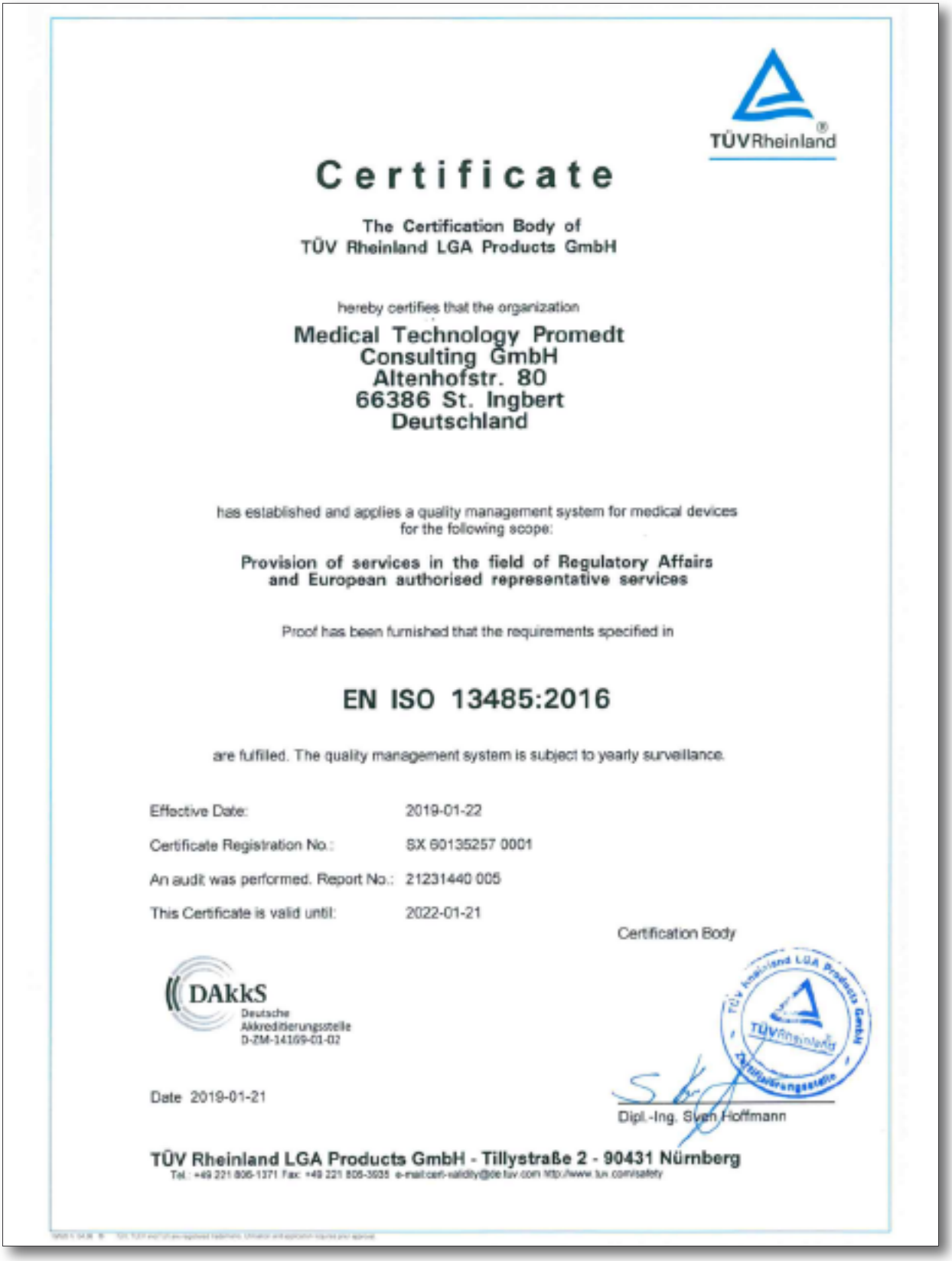
(List of CE marked Products)

Internal Reference Number	Product Name (Model name)	Registration Number (at the German CA/DIMDI) DE/CA70/40838/	Product Category (EDMS)	EDMS Code Description	Classification Annex
CAL-01	All*Check* COVID-19 IgG/IgM	158881	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
CAL-01-01	LabGun™ COVID-19 IgG/IgM	158881	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
CAL-01-02	EZSpeed COVID-19 IgG/IgM	158881	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
CAL-01-03	DNALINK FIND COVID19	158881	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
CAL-01-04	AllCheck COVID19 Ag	158881	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
CAL-01-25	AccuFind COVID19™ Ag	158881	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
CAL-02	DxReal COVID-19 Detection Kit	156425	15 04 40 90 00	Other Virology - NA Reagents	Other IVD / Annex III
CAL-03	AllCheck Influenza A+B	158867	15 04 80 04 00	Influenza & Para Influenza	Other IVD / Annex III

4 November 2020

Dr. Michael Rinck
- Managing Director -

Certificate
Medical Technology Promedt Consulting GmbH



TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Medical Technology Promedt Consulting GmbH
Altenhofstr. 80
66386 St. Ingbert
Deutschland

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

Provision of services in the field of Regulatory Affairs and European authorised representative services

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2019-01-22
Certificate Registration No.:	SX 60135257 0001
An audit was performed. Report No.:	21231440 005
This Certificate is valid until:	2022-01-21

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-01-21

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3035 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate
EC Declaration of Conformity

EC Declaration of Conformity

Manufacturer	CALTH Inc. #321, 54 Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, 13449, Republic of Korea
Manufacturing site	CALTH Inc #7508, 140, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14057, Republic of Korea
EC Representative	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
Product Names (Model Names)	All*Check* COVID19 Ag(CHR11)
Classification	Other Device of IVDD 98/79/EC (no Annex II, List A+B product, no self-testing product)
Conformity Assessment Route	IVDD 98/79/EC Annex III
EDMA Code	15 70 90 90 00

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 documentation is retained under the premises of the manufacture. And Manufacturer is exclusively responsible for the declaration of conformity.

Harmonized Standards

EN ISO13485:2016, EN 13612:2002, EN ISO 23640:2015, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13975:2003, EN 13641:2002, EN ISO 15223-1:2016, EN 62366:2008

Start date of CE marking Sep 29, 2020

CE

In-Vitro Diagnostic Medical Devices
CALTH
CALTH Inc.

Signature: _____

Dong Ho Lee / CEO

CH-F-732-03(Rev.0)

Declaration of Conformity No. CH-DOC-COV03
Issued Date: Sep 29, 2020(R0)

Material Safety Data Sheet (MSDS)

1. General Information.

Trade Name:	**All*Check* COVID19 Ag**
Chemical Family:	In vitro diagnostic Test kit (Rapid tests)
Formula:	N/A
Manufacturer:	CALTH Inc.
Manufacturer's address:	#7508, 140, Beolmal-ro, Dongan-gu, Anyang-si, Gyeinggi-do, Republic of Korea
Phone number:	+82-31-360-0328
Fax number:	+82-70-8228-0328
E.mail:	info@thecalth.com

2. Composition, Information on Active Ingredients

Ingredient	CAS No.	Involve
Control region : Goat anti-Mouse IgG	-	-
Test region : COVID-19 recombinant Nucleocapsid protein antibody	-	-
Sodium Tetraborate	1303-96-4	0.1M
Sodium Azide	26628-22-8	0.1%
Triton X-100	9002-93-1	1%

3. Hazard Information

Hazard description:

The test strip contained in the device is not classified as dangerous.

Information concerning particular hazards for human and environment:

Under the recommended conditions of use, there is no risk of exposure to any of the materials contained in the device.

Calth I AllCheck Covid-19 Ag

One Step Rapid Test

b-to-b

meryll

Kontakt / Contact

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Germany

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Am Kronberger Hang 2
65824 Schwalbach am Taunus
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