**Langue du certificat**
**Taal van het certificaat**
**Sprache des Zertifikats**
**Language of the certificate**

Nederlands / Engels

Gelieve het e-mailadres in te vullen voor de **elektronische versie.**
*Please enter the email address for an **electronic version.***

ecrep@qbdgroup.com

FEDERAAL AGENTSCHAP VOOR GENEESMIDDELEN EN GEZONDHEIDSPRODUCTEN (FAGG)
*FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)*

# CERTIFICAAT VAN VRIJE VERKOOP

# *FREE SALE CERTIFICATE*

Artikel 22/1 - wet van 15 juni 2022 betreffende medische hulpmiddelen voor in-vitrodiagnostiek
**Fabrikant / gemachtigde - hulpmidelen onder IVDD**
**Distributeur / invoerder / uitvoerder - hulpmiddelen onder IVDD en IVDR**

*Article 22/1 - law of 15 June 2022 on in vitro diagnostic medical devices*
***Manufacturer / authorised representative - devices under IVDD***
***Distributor / importer / exporter - devices under IVDD and IVDR***

n° van certificaat / *n° of certificate*: **FAMHP-25-** 1520

Land van uitvoer (certificerend land) / *Exporting (certifying) country*: **Belgium**

Land van invoer (verzoekend land):
*Importing (requesting) country:*

Vietnam

**UITSLUITEND VOOR DE ADMINISTRATIE** Met dit document wordt verklaard dat de fabrikant of zijn gemachtigde (zie punt 1) zijn hoofdkantoor in België heeft en dat het hulpmiddel (zie punt 2) dat voorzien is van een CE-markering overeenkomstig Verordening 2017/746, in de Unie in de handel gebracht mag worden. **Het officiële document van het FAGG is een elektronische versie. Elke gedrukte versie is een transcriptie van deze elektronische versie. Om de juistheid en de integriteit van de informatie te garanderen, moet u altijd de elektronische versie raadplegen, die als de officiële referentie wordt beschouwd.**

***RESERVED FOR THE ADMINISTRATION*** *This document certifies that the manufacturer or his authorised representative (see point 1) has his head office in Belgium and that the device (see point 2) bearing the CE-mark in accordance with Regulation 2017/746, may be placed on the market in the Union.* ***The official document issued by the FAMHP is an electronic version. Any printed version represents a transcription of this electronic version. To ensure the accuracy and integrity of the information, please always consult the electronic version, which is considered the official reference.***

| | |
|---|---|
| Adres van de certificeringsautoriteit:<br>*Address of certifying authority:* | FEDERAAL AGENTSCHAP VOOR GENEESMIDDELEN EN GEZONDHEIDSPRODUCTEN<br>Galileelaan, 5/03, 1210 BRUSSEL (BELGIE)<br>Telefoonnummer: +32 2 528.40.00 |
| Date: 08/09/2025<br><br>Stempel/*Stamp*:<br><br>Agence fédérale des médicaments et des produits de santé (AFMPS) | Naam bevoegd persoon / *Name of authorized person:*<br>Hugues Malonne<br>Administrateur-generaal / *Chief Executive Officer*<br>P.O. Lise Deblecker<br>Head of entity<br>DG POST - Health products<br>Stakeholders support entity<br><br>Digitally signed by: Lise Deblecker<br>(Signature)<br>Date: 2025.09.10 16:26:33 +02'00' |

Moet dit certificaat worden gelegaliseerd door de FOD Buitenlandse Zaken?
*Does this certificate have to be e-legalised by the FPS Foreign Affairs?*

Ja/Yes

Geef het e-mailadres op waarnaar de betalingsaanvraag voor de legalisatie en de gelegaliseerde certificaten moeten worden gestuurd:
*Please provide the email address where the payment request for the legalisation and the legalised certificates should be sent:*

ecrep@qbdgroup.com

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI BỈ
EMBASSY OF THE S.R OF VIETNAM IN BELGIUM

**CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ**
***CONSULAR AUTHENTICATION***

**1. Quốc gia** **VIỆT NAM**
*Country* *Vietnam*

**Giấy tờ, tài liệu này**
*This public document*

**2. do Ông (Bà)** ..... **Veldeman Martine** ..... **ký**
*has been signed by*

**3. với chức danh** ..... **Viên chức lãnh sự** .....
*Acting in the capacity of: Consular Officer*

**4. và con dấu của** ..... **Bộ Ngoại giao Vương quốc Bỉ** .....
*bears the seal/stamp of*

.....

**được chứng nhận/hợp pháp hóa lãnh sự**
*Certified*

**5. tại** **Brúc-xen** **6. Ngày 22 / 09 / 2025**
*at* *the*

**7. Cơ quan cấp ĐSQ CHXHCN VIỆT NAM TẠI BỈ**
*by*

**8. Số 733/2025 - CNLS/HPHLS**
*N°*

**TL. Đại sứ/ For the Ambassador**
**Tham tán/Counsellor**

Nguyễn Bá Sang

B 00676891 B 00676891

## LEGALISATIE - LEGALISATION - LEGALISATION

Gezien voor de legalisatie van de handtekening van :
Vu pour légalisation de la signature de :
Gesehen zur Legalisation der Unterschrift von :
***Deblecker Lise***

Onder Nr./Sous le n°/Unter Nr. : ***250925902152***

Te/A/In : ***Brussel/Bruxelles/Brüssel*** Op/Le/Am : ***11/09/2025***

Stempel/Sceau/Stempel: Ondertekening/Signature/Unterschrift:

Veldeman Martine

Document/Document/Dokument ***Attest/certificaat/Attestation/certificat/Bescheinigung***

Prijs/Prix/Preis: ***20*** EUR

Deze legalisatie waarborgt de authenticiteit van de inhoud van het document niet.
Cette légalisation ne garantit pas l'authenticité du contenu du document.
Diese Legalisation dient nicht dem Beweis des Authentizität des Inhalts des Dokuments.
Deze legalisatie controleren? Vérifier cette légalisation? Diese Legalisation überprüfen?
https://legalweb.diplomatie.be

## 1. Informatie over de aanvrager, fabrikant en de gemachtigde
***Information regarding the applicant, the manufacturer and the authorised representative***

**1.1.1.** Aanvrager: naam en adres:
Applicant: name en address:

QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk
Belgium

**1.1.3** BTW-nummer:
*VAT number:*

BE 0471.352.395

**1.2.1.** Fabrikant (volgens de definitie van Verordening 2017/746): naam en adres:
*Manufacturer (according to the definition of Regulation 2017/746): name and address:*

Shanghai Kehua Bio-engineering Co., Ltd.
1189 North Qinzhou Road
200233 Shanghai
China

**1.2.2** BTW-nummer:
*VAT number:*

N/A

**1.2.3** SRN:
*SRN:*

CN-MF-000026756

**1.3.1.** Gemachtigde (volgens de definitie van Verordening 2017/746 - indien van toepassing) naam en adres:
*Authorised representative (according to the definition of Regulation 2017/746 - if applicable) name and address:*

QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk
Belgium

**1.3.2** BTW-nummer:
*VAT number:*

BE 0471.352.395

**1.3.3** SRN:
*SRN:*

BE-AR-000026[illegible]

| | |
|---|---|
| ***1.4.*** *Is de fabrikant gecertificeerd volgens de ISO 9001/ EN 13485-normen?*<br>*Has the manufacturer been certified to be in compliance with ISO 9001/ EN 13485 standards?* | *Ja/Yes* |
| Zo ja, vermeld de naam van de organisatie die het certificaat heeft afgeleverd:<br>*If yes state the name of the organisation that delivered the certificate:* | TÜV SÜD Product Service GmbH |

## 2. Naam en vorm van het/de product(en)
## *Name and form of product(s):*

**2.1.** Classificatie van het hulpmiddel/de hulpmiddelen:
*Classification of the device(s):*

Directive 98/79/EC - Other

**Oude hulpmiddelen**
***Legacy devices***

| **Notificatienummer** *Notification number** | **Hulpmiddelnaam (-namen)** *Device name(s)* | **geef aan in welke klasse het hulpmiddel (de hulpmiddelen) zal/zullen vallen onder Verordening 2017/746** *please specify which class should the device(s) be under the regulation 2017/746* |
|---|---|---|
| BE/CA01/1-17773-00044-IVD | Thyroid-stimulating Hormone Quantitative Detection KIT(Chemiluminescent Immunoassay) (REF: KH-G-L-317-04-CE, KH-G-L-317-01-CE, KH-G-L-317-02-CE, KH-G-L-317-03-CE) | Class B |
| BE/CA01/1-17773-00045-IVD | Total Triiodothyronine Quantitative Detection KIT(Chemiluminescent Immunoassay) (REF: KH-G-L-314-04-CE, KH-G-L-314-01-CE, KH-G-L-314-02-CE, KH-G-L-314-03-CE) | Class B |
| BE/CA01/1-17773-00046-IVD | Total Thyroxine Quantitative Detection KIT(Chemiluminescent Immunoassay) (REF: KH-G-L-313-03-CE, KH-G-L-313-01-CE, KH-G-L-313-02-CE) | Class B |
| BE/CA01/1-17773-00047-IVD | Free Triiodothyronine Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-316-04-CE, KH-G-L-316-01-CE, KH-G-L-316-02-CE, KH-G-L-316-03-CE) | Class B |
| BE/CA01/1-17773-00048-IVD | Free Thyroxine Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-315-03-CE, KH-G-L-315-01-CE, KH-G-L-315-02-CE) | Class B |
| BE/CA01/1-17773-00049-IVD | Antibody to Thyroglobulin Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-334-04-CE, KH-G-L-334-01-CE, KH-G-L-334-02-CE, KH-G-L-334-03-CE) | Class B |
| BE/CA01/1-17773-00050-IVD | Antibodies to Thyroid Peroxidase Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-335-04-CE, KH-G-L-335-01-CE, KH-G-L-335-02-CE, KH-G-L-335-03-CE) | Class B |
| BE/CA01/1-17773-00051-IVD | Alpha1-fetoprotein Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-301-03-CE, KH-G-L-301-01-CE, KH-G-L-301-02-CE) | Class C |
| BE/CA01/1-17773-00052-IVD | Carcinoembryonic Antigen Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-303-04-CE, KH-G-L-303-01-CE, KH-G-L-303-02-CE, KH-G-L-303-03-CE) | Class C |
| BE/CA01/1-17773-00053-IVD | Cancer Antigen 125 Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-302-04-CE, KH-G-L-302-01-CE, KH-G-L-302-02-CE, KH-G-L-302-03-CE) | Class C |
| BE/CA01/1-17773-00054-IVD | Cancer Antigen 15-3 Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-328-04-CE, KH-G-L-328-01-CE, KH-G-L-328-02-CE, KH-G-L-328-03-CE) | Class C |
| BE/CA01/1-17773-00055-IVD | Carbohydrate Antigen 19-9 Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-306-04-CE, KH-G-L-306-01-CE, KH-G-L-306-02-CE, KH-G-L-306-03-CE) | Class C |
| BE/CA01/1-17773-00056-IVD | Ferritin Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-307-04-CE, KH-G-L-307-01-CE, KH-G-L-307-02-CE, KH-G-L-307-03-CE) | Class C |
| BE/CA01/1-17773-00057-IVD | Luteotropic Hormone Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-325-04-CE, KH-G-L-325-01-CE, KH-G-L-325-02-CE, KH-G-L-325-03-CE) | Class B |
| BE/CA01/1-17773-00058-IVD | Follicle-stimulating Hormone Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-324-04-CE, KH-G-L-324-01-CE, KH-G-L-324-02-CE, KH-G-L-324-03-CE) | Class B |

| **Notificatienummer**<br>***Notification number**** | **Hulpmiddelnaam (-namen)**<br>***Device name(s)*** | **geef aan in welke klasse het hulpmiddel (de hulpmiddelen) zal/zullen vallen onder Verordening 2017/746**<br>***please specify which class should the device(s) be under the regulation 2017/746*** |
|---|---|---|
| BE/CA01/1-17773-00085-IVD | Squamous-cell Carcinoma Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-350-04-CE, KH-G-L-350-01-CE, KH-G-L-350-02-CE, KH-G-L-350-03-CE) | Class C |
| BE/CA01/1-17773-00086-IVD | Human Epididymis Protein 4 Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-346-04-CE, KH-G-L-346-01-CE, KH-G-L-346-02-CE, KH-G-L-346-03-CE) | Class C |
| BE/CA01/1-17773-00087-IVD | Pepsinogen I Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-351-05-CE, KH-G-L-351-01-CE, KH-G-L-351-02-CE, KH-G-L-351-03-CE, KH-G-L-351-04-CE) | Class C |
| BE/CA01/1-17773-00088-IVD | Pepsinogen II Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-352-05-CE, KH-G-L-352-01-CE, KH-G-L-352-02-CE, KH-G-L-352-03-CE, KH-G-L-352-04-CE) | Class C |
| BE/CA01/1-17773-00089-IVD | Prolactin Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-326-04-CE, KH-G-L-326-01-CE, KH-G-L-326-02-CE, KH-G-L-326-03-CE) | Class B |
| BE/CA01/1-17773-00090-IVD | Estradiol Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-341-04-CE, KH-G-L-341-01-CE, KH-G-L-341-02-CE, KH-G-L-341-03-CE) | Class B |
| BE/CA01/1-17773-00091-IVD | Progesterone Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-339-04-CE, KH-G-L-339-01-CE, KH-G-L-339-02-CE, KH-G-L-339-03-CE) | Class B |
| BE/CA01/1-17773-00092-IVD | Testosterone Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-340-04-CE, KH-G-L-340-01-CE, KH-G-L-340-02-CE, KH-G-L-340-03-CE) | Class B |
| BE/CA01/1-17773-00093-IVD | Beta Human Chorionic Gonadotropin Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-323-04-CE, KH-G-L-323-01-CE, KH-G-L-323-02-CE, KH-G-L-323-03-CE) | Class B |
| BE/CA01/1-17773-00094-IVD | N-terminal Pro B-type Natriuretic Peptide Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-345-04-CE, KH-G-L-345-01-CE, KH-G-L-345-02-CE, KH-G-L-345-03-CE) | Class C |
| BE/CA01/1-17773-00095-IVD | Procalcitonin Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-332-04-CE, KH-G-L-332-01-CE, KH-G-L-332-02-CE, KH-G-L-332-03-CE) | Class C |
| BE/CA01/1-17773-00096-IVD | Interleukin-6 Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-376-07-CE, KH-G-L-376-01-CE, KH-G-L-376-02-CE, KH-G-L-376-03-CE, KH-G-L-376-04-CE, KH-G-L-376-05-CE, KH-G-L-376-06-CE) | Class C |
| BE/CA01/1-17773-00097-IVD | Insulin Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-318-04-CE, KH-G-L-318-01-CE, KH-G-L-318-02-CE, KH-G-L-318-03-CE) | Class C |
| BE/CA01/1-17773-00098-IVD | Connecting Peptide Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-319-04-CE, KH-G-L-319-01-CE, KH-G-L-319-02-CE, KH-G-L-319-03-CE) | Class C |
| BE/CA01/1-17773-00099-IVD | Thyroglobulin Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-32J-01-CE, KH-G-L-32J-02-CE, KH-G-L-32J-03-CE, KH-G-L-32J-04-CE) | Class B |
| BE/CA01/1-17773-00100-IVD | Neuron-specific Enolase Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-369-03-CE, KH-G-L-369-01-CE, KH-G-L-369-02-CE) | Class C |

| **Notificatienummer**<br>***Notification number**** | **Hulpmiddelnaam (-namen)**<br>***Device name(s)*** | **geef aan in welke klasse het hulpmiddel (de hulpmiddelen) zal/zullen vallen onder Verordening 2017/746**<br>***please specify which class should the device(s) be under the regulation 2017/746*** |
|---|---|---|
| BE/CA01/1-17773-00101-IVD | Cyfra21-1 Quantitative Detection KIT (Chemiluminescent Immunoassay) (REF: KH-G-L-330-05-CE, KH-G-L-330-01-CE, KH-G-L-330-02-CE, KH-G-L-330-03-CE, KH-G-L-330-04-CE) | Class C |

* Voor klasse I, gelieve het notificatienummer te vermelden.
Als het (de) hulpmiddel(en) geregistreerd is (zijn) in Eudamed, vermeld dan "EUDAMED".
**For class I, please provide the notification number.*
*If the device(s) is/are registered in Eudamed, please indicate "EUDAMED"*

Een lijn toevoegen - Add a line | Een lijn verwijderen - Remove a line

| | |
|---|---|
| **2.2.** Mag dit product op de markt worden gebracht voor gebruik in het exporterende land?<br>*Is this product authorized to be placed on the market for use in the exporting country?* | Ja/Yes |
| **2.3.** Is dit product daadwerkelijk op de markt in het exporterende land?<br>*Is this product actually on the market in the exporting country?* | Nee/No |
| **2.4.** Is het geëxporteerde product voorzien van de CE-markering?<br>*Does the exported product carry the CE mark ?* | Ja/Yes |