



contact

Centrum Menselijke Erfelijkheid (CME), UZ Leuven

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VAT No.: BE 0419.052.173

NIHDI (RIZIV) erkenningsnummer : 8-24990-92-996

BELAC accreditation certificate: 215-MED (EN ISO 15189:2022)

**Declaration of Compliance with NIHDI (RIZIV) recognition criteria, ISO 15189
Accreditation and IVDR Requirements**

We hereby declare compliance with the following quality standards and requirements:

1. Certification by NIHDI (RIZIV)

Our laboratory is registered with the National Institute for Health and Disability Insurance (NIHDI/RIZIV) under registration number 8-24990-92-996.

In Belgium, for reimbursement of patient bills by the Social Security System, federal law requires conformity to the standards of a quality system according to Royal Decree of 14 December 1988.

Adequate procedural documentation and validation of laboratory instrumentation and participation in an external quality control scheme organized by Sciensano (with mailing of survey specimens each trimester) are required to uphold certification status.

2. Accreditation by BELAC as a medical laboratory

The Centre for Human Genetics (CME) is accredited by BELAC pursuant to Articles 33, 33bis and 33ter as a medical laboratory. BELAC is part of the FPS Economy, SMEs, Self-employed and Energy, Directorate-General Quality and Safety - Accreditation, Boulevard du Roi Albert II 16, 5th floor, 1000 Brussels.

The accreditation is granted in accordance with NBN EN ISO 15189:2022. A copy of our most recent accreditation certificate (Certificate No. 215-MED, subject to periodic surveillance) is enclosed.

The accreditation applies to the analyses listed in the BELAC scope table, which can be consulted on the BELAC website². Whether a specific test is performed under accreditation can be verified in the laboratory guide³ available through the CME website¹.

3. Compliance with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

In relation to the IVDR 2017/746 regulation, UZ Leuven laboratories as a 'health institution' fall under the exception of article 5.5 regarding the use of in-house developed tests. The following policy is applied within UZ Leuven laboratories:

When no suitable CE-marked in-vitro diagnostics (IVDs) are available on the market to deliver the specialized and innovative care we strive for, UZ Leuven may choose to develop and manufacture its own IVDs. These in-house developed IVDs can only be used if the requirements of article 5.5 of IVDR 2017/746 are met.

In addition to the NIHDI (RIZIV) recognition and ISO 15189 accreditation described above, the quality management system of the UZ Leuven medical laboratories has been supplemented to incorporate the requirements of IVDR 2017/746 applicable to in-house developed tests.

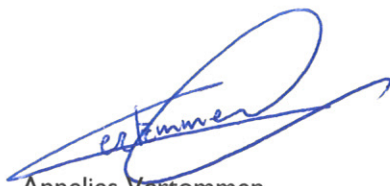
- ¹. CME website: <https://www.uzleuven.be/en/centre-human-genetics>
- ². BELAC website: <http://economie.fgov.be/belac>
- ³. link to lab guide: <https://www.uzleuven.be/en/centre-human-genetics/request-diagnostic-test>



Prof. dr. Geert Mortier
diensthoofd CME-UZ



Prof. E. Dequeker
Regulatory Affairs Officer voor IVDR



Annelies Vertommen
Kwaliteitsverantwoordelijke CME



Organisme belge d'Accréditation
Belgische Accreditatieinstelling
Belgische Akkreditierungsstelle
Belgian Accreditation Body

EA MLA Signatory

Certificat d'Accréditation n° 215-MED

En application des dispositions de l'arrêté royal du 31 janvier 2006 créant BELAC, le Bureau d'Accréditation atteste avoir délivré une accréditation conformément aux exigences de la norme EN ISO 15189:2022 à:

**Katholieke Universiteit te Leuven
KU Leuven
Oude Markt 13
3000 Leuven**

Numéro d'entreprise: 0419.052.173

L'organisme a démontré posséder la compétence pour effectuer les activités réalisées dans les sites d'activités mentionnés dans la portée d'accréditation 215-MED qui fait partie intégrante du présent certificat.

La version en vigueur de la portée d'accréditation est disponible via www.belac.be.

Ce certificat reste valable à condition que l'organisme continue de répondre aux conditions d'accréditation.

La Présidente du Bureau d'Accréditation BELAC,

Maureen LOGGHE

Version : 11

Période de validité : 2026-02-03 - 2031-02-02

La version originale de ce certificat est en néerlandais.



Organisme belge d'Accréditation
Belgische Accreditatieinstelling
Belgische Akkreditierungsstelle
Belgian Accreditation Body

EA MLA Signatory

Accreditatiecertificaat nr. 215-MED

In uitvoering van de beschikkingen van het koninklijk besluit van 31 januari 2006 tot oprichting van BELAC, verklaart het Accreditatiebureau accreditatie conform de eisen van de norm EN ISO 15189:2022 te hebben verleend aan:

**Katholieke Universiteit te Leuven
KU Leuven
Oude Markt 13
3000 Leuven**

Ondernemingsnummer: 0419.052.173

De instelling heeft aangetoond bekwaamheid te bezitten voor de activiteiten uitgevoerd in de activiteitencentra zoals gespecificeerd in de accreditatiescope 215-MED die integraal deel uitmaakt van dit certificaat.

De huidige versie van de accreditatiescope is beschikbaar op www.belac.be.

Dit certificaat blijft geldig onder voorwaarde dat de instelling blijft voldoen aan de accreditatievoorwaarden.

De Voorzitster van het Accreditatiebureau BELAC,

Maureen LOGGHE

Versie : 11

Geldigheidsduur : 2026-02-03 - 2031-02-02



Organisme belge d'Accréditation
Belgische Accreditatieinstelling
Belgische Akkreditierungsstelle
Belgian Accreditation Body

EA MLA Signatory

Accreditation Certificate No. 215-MED

In compliance with the provisions of the Royal Decree of 31 January 2006 setting up BELAC, the Accreditation Board hereby declares to have granted accreditation conform the requirements of the standard EN ISO 15189:2022 to:

**Katholieke Universiteit te Leuven
KU Leuven**

Oude Markt 13

3000 Leuven

Enterprise number: 0419.052.173

The body demonstrated the competence to perform the activities in the activity sites, as described in the scope of accreditation 215-MED which is an integral part of the present certificate.

The current version of the scope of accreditation is available at www.belac.be.

This certificate remains valid as long as the body continues to meet the accreditation conditions.

The Chair of the Accreditation Board BELAC,

Maureen LOGGHE

Version : 11

Validity period : 2026-02-03 - 2031-02-02

Original version of this certificate is in Dutch.



Organisme belge d'Accréditation
Belgische Accreditatieinstelling
Belgische Akkreditierungsstelle
Belgian Accreditation Body

EA MLA Signatory

Akkreditierungszertifikat Nr. 215-MED

Aufgrund der Bestimmungen des königlichen Erlasses vom 31. Januar 2006 zur Gründung von BELAC, bestätigt das Akkreditierungsbüro, gemäß den Vorschriften der Norm EN ISO 15189:2022, die folgende Stelle akkreditiert zu haben:

**Katholieke Universiteit te Leuven
KU Leuven
Oude Markt 13
3000 Leuven**

Unternehmensnummer: 0419.052.173

Die Stelle hat ihre Kompetenz für die in den Aktivitätszentren durchgeführten Aktivitäten gemäß dem Geltungsbereich der Akkreditierung 215-MED, der ein integraler Bestandteil des vorliegenden Zertifikats ist, nachgewiesen.

Die aktuelle Version des Geltungsbereichs der Akkreditierung ist unter www.belac.be verfügbar.

Dieses Zertifikat bleibt unter der Bedingung gültig, dass die Stelle die Akkreditierungsanforderungen weiterhin erfüllt.

Die Vorsitzende des Akkreditierungsbüros BELAC,

Maureen LOGGHE

Fassung : 11

Gültigkeitsdauer : 2026-02-03 - 2031-02-02

Die Originalfassung dieses Zertifikats ist in niederländischer Sprache.