

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN



MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **IVDB8128921-67256**
Registration No.:

Tarikh Sah Pendaftaran: **16/07/2021 - 15/07/2026**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada:
This certificate is hereby issued to:

UBISSON SDN BHD

yang beralamat di:
which is located at:

**NO. 35, LOT 2735, 1ST & 3RD FLOOR, PUSAT
PEDADA, JALAN PEDADA,
96000
SIBU SARAWAK BUMI KENYALANG**

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.



AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY



No. Pendaftaran: **IVDB8128921-67256**

Registration No.:

Butir-butir peranti perubatan yang didaftarkan

Particulars of the registered medical device

Nama Peranti Perubatan **QUO-LAB A1C SYSTEM**

Medical Device Name

Kelas **CLASS B** Jenama **EKF**

Class Brand

Kelompok **FAMILY OF SYSTEM**

Group

Displin **Haematology (Blood tests for transfusions excluded)** Kategori **Other Hematology Tests**

Discipline Category

Nama dan alamat pembuat: **EKF-DIAGNOSTIC GMBH
EBENDORFER CHAUSSEE 3, 79179 BARLEBEN, GERMANY,
39179**

Name and address of manufacturer **GERMANY**

APPENDIX

Nama Sistem **EKF QUO-LAB A1C SYSTEM**

System Name

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	EKF Quo-Lab Model No. 0110 (label on device) EKF Quo-Lab Analyzer System 0110-0000 (label on carton box)	0110-000 (catalogue no. 3101-0011_VS)	HbA1c Fluorimeter / Photometer. The Quo-Lab Analyzer is a semi-automated fluorimeter and dual wavelength photometer for measurement of glycated hemoglobin (HbA1c) in whole blood, using a fluorescence quenching technique.
2	EKF Quo-Lab A1C Test Kit (50pcs)	0055 (catalogue no. 3101-3011_VS)	Box of 50 cartridges + 16 sampling sticks. The Quo-Lab A1C Test Kit is an assay for the measurement of glycated hemoglobin in whole blood. The Test Kit consists of the sampling stick and the test cartridge itself containing all the reagents required to perform a single test for the measurement of A1C in capillary or venous blood, without the need for a separation step to differentiate the A1C fraction from other forms of hemoglobin.



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
3	EKF Quo-Lab A1C Test Kit (25pcs)	3101-3051 (catalogue no. 3101-6011_VS)	Box of 25 cartridges + 16 sampling sticks. The Quo-Lab A1C Test Kit is an assay for the measurement of glycated hemoglobin in whole blood. The Test Kit consists of the sampling stick and the test cartridge itself containing all the reagents required to perform a single test for the measurement of A1C in capillary or venous blood, without the need for a separation step to differentiate the A1C fraction from other forms of hemoglobin.
4	EKF Quo-Lab A1C Control Kit	3101-6021_VS (catalogue no. 3101- 6201_VS)	Box of 4 Control solutions (2 x Level 1, 2 x Level 2) + 5 single use ampoules of reconstitution fluid. The Quo-Lab A1C Control Kit is a two-level, lyophilized control, which is used with the Quo-Lab A1C Test Cartridges for quality control to ensure that the system is operating correctly.
5	Label Printer	3100-7101-0409	Optional printer for Quo-Test / Quo-Lab analyzer with connector cable; comes with 320 labels
6	Printer labels	7045-7012-0304	Printer labels for use with either Quo-Test / Quo-Lab
7	Barcode scanner	3100-7121-1327	Spare barcode scanner for use with either Quo-Test / Quo-Lab
8	Power cable	3100-7011-0527	Spare power cable for use with either Quo-Test / Quo-Lab
9	Printer cable	3100-7111-0036	Spare printer connection cable for use with either Quo-Test / Quo-Lab
"End Of Product List"			