3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2024-IVDR/QS-004

EXBIO Praha, a.s.
Registered place of business: Nad Safinou II 341, 252 50 Vestec, Czech Republic
Production site: Nad Safinou II 341, 252 50 Vestec, Czech Republic
SRN No.: CZ-MF-000033468

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended confirms, that quality management system of in vitro diagnostic medical device:

Monoclonal Antibodies / Flow Cytometry (IVP 3006)
(For details, see Annex I)
Intended purpose: Annex II
IVD MD class C

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR011_2023 from 29.02.2024, IVD MD Performance Evaluation Assessment Report No. IVDR011_2023 from 29.02.2024 and IVD MD Audit Report No. SK-0739/24 from 06.06.2024. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned in vitro diagnostic medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **04.12.2024**
Valid until: **11.06.2029**
First issue: **11.06.2024**
Revision: **01**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovak Republic, 04.12.2024

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-004

issued for the company

EXBIO Praha, a.s.

Nad Safinou II 341, 252 50 Vestec, Czech Republic

List of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

Product type	Trade Name	Cat. No (REF)
Monoclonal Antibodies / Flow Cytometry	KOMBITEST TBNK 6-color	ED7733
	KOMBITEST T Cell 4-color	ED7734
	KOMBITEST B/NK Cell 4-color	ED7735
	DryFlowEx TBNK 6-color	ED7736
	DryFlowEx PNH High-Sensitivity Assay Kit	ED7750
	CD34 QuantiFlowEx Kit	ED7080

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 04.12.2024
Valid until 11.06.2029

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-004

issued for the company

EXBIO Praha, a.s.

Nad Safinou II 341, 252 50 Vestec, Czech Republic

Intended purpose of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

KOMBITEST TBNK 6-color is intended for detection and enumeration of lymphocyte populations and subsets in human whole blood by flow cytometry.

KOMBITEST T Cell 4-color is intended for detection and enumeration of lymphocyte populations and subsets in human whole blood by flow cytometry.

KOMBITEST B/NK Cell 4-color is intended for detection and enumeration of lymphocyte populations and subsets in human whole blood by flow cytometry.

DryFlowEx TBNK 6-color is intended for detection and enumeration of lymphocyte populations and subsets in human whole blood by flow cytometry.

DryFlowEx PNH High-Sensitivity Assay Kit is intended for high sensitivity detection and enumeration of glycosyl-phosphatidyl-inositol (GPI)-deficient cells in human whole blood by flow cytometry.

CD34 QuantiFlowEx Kit is intended for detection and enumeration of total viable hematopoietic stem cells from total viable leukocytes in human blood and tissue samples by flow cytometry.

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 04.12.2024
Valid until 11.06.2029

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-004

issued for the company

EXBIO Praha, a.s.

Nad Safinou II 341, 252 50 Vestec, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2024-IVDR/QS-004	11.06.2024	IVDR011_2023 IVDR025_2024	Initially granted certification
01	2024-IVDR/QS-004	04.12.2024	IVDR023_2024 IVDR024_2024 IVDR026_2024 IVDR027_2024	scope extension

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 04.12.2024
Valid until 11.06.2029