3EC®
international

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-IVDR/QS-002

EXBIO Praha, a.s.
Registered place of business: Nad Safinou II 341, 252 50 Vestec, Czech Republic
Manufacturing 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:

BasoFlowEx Kit
Other devices intended to be used to define or monitor physiological status and therapeutic measures (IVR0609)
Intended purpose: See Annex II
IVD MD class B
(detailed list is stated in the annex(es) if applicable)

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. IVDR028_2024 from 19.03.2025, IVD MD Performance Evaluation Assessment Report No. IVDR028_2024 from 19.03.2025 and IVD MD Audit Report No. SK-0739/25 from 30.05.2025. 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: **03.06.2025**
Valid until: **11.06.2029**
First issue: **03.06.2025**
Revision: **00**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 03.06.2025

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-002

issued for the company

EXBIO Praha, a.s.

Registered place of business: Nad Safinou II 341, 252 50 Vestec, Czech Republic
Manufacturing site: Nad Safinou II 341, 252 50 Vestec, Czech Republic

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

Trade Name	REF
BasoFlowEx Kit	ED7043

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 03.06.2025
Valid until 11.06.2029

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-002

issued for the company

EXBIO Praha, a.s.

Registered place of business: Nad Safinou II 341, 252 50 Vestec, Czech Republic
Manufacturing site: 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:

BasoFlowEx Kit is intended for the determination of basophil activation in peripheral whole blood by flow cytometry.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 03.06.2025
Valid until 11.06.2029

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-002

issued for the company

EXBIO Praha, a.s.

Registered place of business: Nad Safinou II 341, 252 50 Vestec, Czech Republic
Manufacturing site: 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	2025-IVDR/QS-002	03.06.2025	IVDR028_2024	Initially granted certification

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 03.06.2025
Valid until 11.06.2029