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A Brighter Future in Flow

EU Declaration of Conformity

(According to Annex IV of the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices)

Hereby and with the CE-sign it is confirmed that following product, manufactured by EXBIO Praha, a.s., Nad Safinou II 341, 252 50 Vestec, Czech Republic, complies with all essential requirements of the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices. This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

Product Name	KOMBITEST B/NK Cell 4-color
Cat. No.	ED7735
Manufacturer	EXBIO Praha, a.s., Nad Safinou II 341, 252 50 Vestec, Czech Republic
Single Registration Number	CZ-MF-000033468
Intended Use	KOMBITEST B/NK Cell 4-color is intended for detection and enumeration of lymphocyte populations and subsets in human whole blood by flow cytometry.
Intended User	The device is intended for professional laboratory use only.
UDI-DI (GTIN)	8594208060031
Basic UDI-DI	859420806ED773578
Risk-Based Classification	Class C, Rule 3 (e)
GMDN Code	56917
EMDN Code	W0103080106
Notified Body Number	2265
Notified Body Name	3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Conformity assessment procedure performed	Annex IX of the Regulation (EU) 2017/746 Conformity assessment based on a quality management system and on assessment of technical documentation
Identification of the issued certificate	EU Quality Management System Certificate No. 2024-IVDR/QS-004

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EXBIO Praha, a.s. has an established Quality Management System in compliance with the following standards:

ISO 13485:2016	Certificate issued by: Lloyd's Register Nederland B.V. for and on behalf of: Lloyd's Register Quality Assurance Limited
ISO 9001:2015	Certificate issued by: Lloyd's Register EMEA for and on behalf of: Lloyd's Register Quality Assurance Limited

Conformity Assessment Standards and Regulations Applied:

Regulation / Standard	Document Name
Regulation (EU) 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices
Regulation (EC) No 1272/2008	Classification, Labelling and Packaging (CLP) Regulation
EU REACH Regulation (EC) No 1907/2006	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 9001:2015	Quality Management Systems – Requirements
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
ISO/TR 24971:2020	Medical Devices – Guidance on the application of ISO 14971
CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with information to be supplied with medical devices – Part 1: General Requirements
EN ISO 20417:2021	Medical Devices – Information to be supplied by the manufacturer
ISO/TR 20416:2020	Medical Devices – Post-market surveillance for manufacturers

For and on behalf of EXBIO Praha, a.s.

František Škrob
Director, QA & RA Department

Place and Date of issue: Vestec, Czech Republic, 09 December 2024

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