EC Declaration of Conformity

MLT LLC

Tehnologicheskaya St. 7 Dubna, Moscow region, Russia, 141981

SRN: RU-MF-000003044

declares under his sole responsibility that the product

EMDN / Basic UDI-DI:	**W0202059002** / for Class A Article 24(4) shall apply from 26 May 2027
Product names:	**FS-9-25, FS-12-25, FS-16-25, FS-16-HISTO, FS-16-COMBO**
Product group:	**Automated slide stainers**
Intended Purpose:	**IVD medical devices are intended for staining micro preparations on slides for the purpose of further morphological examinations.**

meets the applicable provisions as stated below and the relevant standards and common specification as specified in the technical documentation

Applicable regulation:	**The Regulation (EU) 2017/746 (In Vitro Diagnostic Medical Device Regulation – IVDR)**
Risk class (according to Annex VIII IVDR):	**Class A according to Rule 5 b)**
Conformity assessment procedure:	**Art. 48(10) and Annex IV (Declaration of Conformity) according to Regulation (EU) 2017/746**
Notified body:	**Not applicable**
Notified body no.:	**Not applicable**
EC certificate:	**Not applicable**
Authorized Representative:	**CEpartner4U B.V.**
Address:	**Esdoornlaan 13, 3951 DB Maarn**
Country:	**The Netherlands**

We hereby declare that the medical devices specified above meet the provision of the Regulation (EU) IVDR 2017/746 for *in vitro* diagnostic medical devices. This declaration is supported by the Quality Management Systems approval to ISO 13485:2016 issued by certification body G-CERTI. All supporting documentation is retained at the premises of the manufacturer.

CE

Name:	Alexander Bezrukov
Title:	General Director
Date of issue:	October 10, 2023
Signature:	