



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 System approval to EN ISO 13485:2016 issued by LL-C (Certification). All supporting documentation is retained at the premises of the manufacturer.



Name: Alexander Bezrukov
Title: General Director
Date of issue: April 29, 2022
Signature: 

