MOLDOVA EUROPEANĂ

EU DECLARATION OF CONFORMITY

Manufacturer's Name and Address

Eastern Business Forms, LLC
530 Old Sulphur Springs Rd.
Greenville, SC 29607 USA

Declaration of Conformity

I, Richard Haines, as management's representative and the person responsible for regulatory compliance, and on behalf of EBF who has sole responsibility over issuance of this declaration of conformity, hereby declare that the below described product:

(i) Complies with all requirements of the Regulation EU 2017/746 for *In Vitro* Diagnostic Medical Devices (IVDR),
(ii) Has had its classification updated according to the IVDR classification rules, and
(iii) Conforms to requirements specified in Article 17 and Annex IV EU Declaration of Conformity, with further details as follows:

Registered (US FDA) Proprietary Name:	903 Filter Paper
International Trade Name – as it may appear on devices:	903™
Family/Model Name – as it may appear on Device, Pack Label, or Instructions For Use:	903™ Filter Paper, and/or other unique descriptive names as specified by customers.
Authorized Representative:	CMC Medical Devices & Drugs S.L. C/ Horacio Lengo N18, CP29006, Malaga, Spain +34951214054
Description:	903 Filter Paper (903FP) is an IVD specimen receptacle, customized to suit the dried blood spot (DBS) collection needs of clinical newborn screening (NBS) or adult/child (A/C) testing programs, or other customer specimen collection requirements.
Catalog, Article, Serial Numbers:	Catalog/Article Reference Number(s) are specific to each customer's 903FP device layout/artwork design in optional single- or multi-part, or cassette configurations. Product identification/traceability controlled by unique device identification (UDI); 903FP lot #, job order #, and S/N's which are optional per customer requirements.
Basic GS1/GUDID UDI-DI:	00850039198007 (representing devices made from 903 Filter Paper Lot # W211)
Risk-Based Classification & Rule:	Class A, Rule 5 (single-use, inactive, non-sterile, non-implantable, not self-testing)
GMDN Code:	45522, Blood Collection Paper

Quality Management System Certificate

Conformity Assessment Body Issuing the Certificate:	NQA 289 Great Road, Suite 105 Acton, MA 01720 USA
Standard:	ISO13485:2016
Certificate Number:	17633
Issuance Date:	12/6/2020
Expiry Date:	12/4/2023

Primary Standards Applied

EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 18113-1:2011	European Norm – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 1: Terms, Definitions and General Requirements
EN ISO 15223-1:2021	European Norm – Medical Devices – Symbols for Use with Medical Device Labels, Labelling and Information to be Supplied
CLSI NBS01-7E	Clinical & Laboratory Standards Institute – Blood Collection on Filter Paper for NBS Programs

Place and Date of Issue

Location / Date:	Name, Position and Signature of Responsible Person
Greenville, SC USA / 3/23/2022	R. Haines (on behalf of EBF Top Management) Quality/Regulatory Manager