

**MO 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, Troy Lee, 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 Law No. 102 from 09.06.2017 regarding medical devices (with legacy reference of registration and conformity to 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:	GBG-MLD SRL Str. Albisoara 64/2, Moldova +022-207839
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:	00850039198021 (representing devices made from 903 Filter Paper Lot # W221)
Risk-Based Classification & Rule:	Class A, Rule 5 (single-use, inactive, non-sterile, non-implantable, not self-testing)
GMDN Code:	45522, Blood Collection Paper

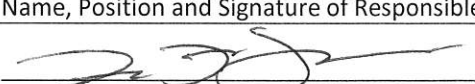

**Quality Management System Certificate**

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 / 8/16/2023	 T. Lee (on behalf of EBF Top Management), Quality/Regulatory Manager 



## LETTER OF AUTHORIZATION

August 14, 2023

To: Medicines and Medical Devices Agency

We, Eastern Business Forms, LLC

having a registered office at 530 Old Sulphur Springs Rd, Greenville, South Carolina 29607 USA, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Moldova, as **Authorized representative** in correspondence with the conditions of LAW No. 102 from 09.06.2017 regarding medical devices.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Greenville, SC

Date: 8/21, 2023

Signed: \_\_\_\_\_



903 Neonatal Moldova Card  
10535146 Rev.AB  
Job # 7209721-001  
04-16-21  
First Proof

 **903 Neonatal Moldova Card**

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200 Cards per Pack 903™

REF 10535146 Rev AB  2026-04-30 LOT 7209721 W201

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1) Do not touch sample area    2) Do not use if damaged

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 **EASTERN**  
BUSINESS FORMS, INC.  
530 Old Sulphur Springs Rd  
Greenville, SC 29607 USA

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 (01) 00860802000383  
(02) 200 (10) 7209721/W201  
(17) 2026-04-30

Approved As Is  
 Not Approved, Show Another Proof

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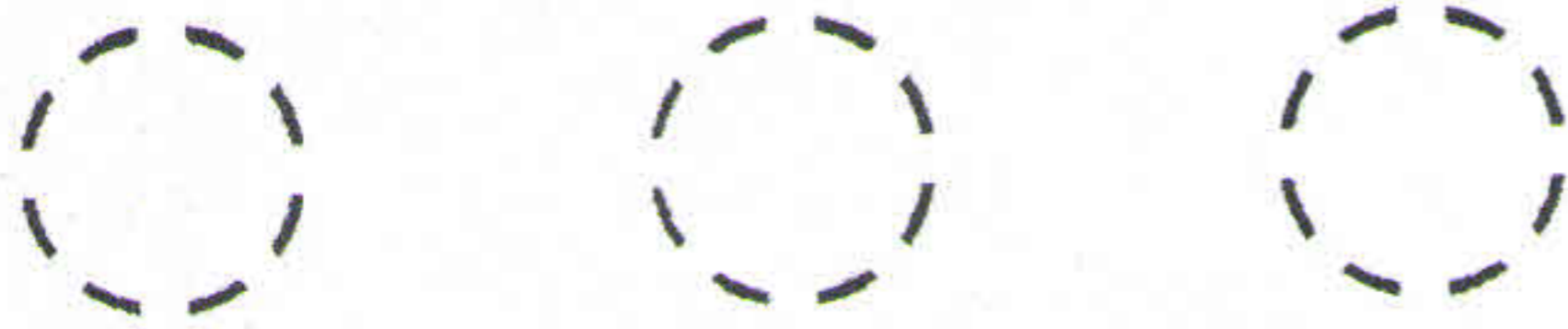
Signature *M. Usurelu*

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Date *03.05.2022*



White Thermal Transfer Label  
with Permanent Adhesive  
3" x 3" (76.2mm x 76.2mm)  
Prints Reflex Blue, Red 185  
and Black Thermal Ink



Не дотрагивайтесь до области внутри кружков  
Не используйте поврежденные тест-бланки

Кружки на бланке пропитывают  
равномерно, обильно и аккуратно,  
по одной капле крови на каждый  
кружок, взятой обычным способом  
из пятки. Капли могут быть больше  
чем кружки, но ни в коем случае  
меньше. Кровяные пятна  
высушиваются на воздухе.

Леч. учреждение

Ф.И.О. матери

пол:

Ф.И.О. ребенка

Жен.

Муж.

Дата рождения

Вес при рождении

Дата взятия пробы

Нормальная беременность ?  
Недоношенный ?

Антибиотики ? Асфикция ?  
Сульфонамиды ? Желтуха ?

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



903™

2026-04-30

REF

10535146  
Rev.AB

LOT

7209721  
W201

903 Neonatal Moldova Card  
10535146 Rev.AB  
Job # 7209721-002  
04-26-21  
Second Proof

CUSTOMER	
APPROVED	<input checked="" type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	<i>N. Usurelu</i>
NAME:	<i>Dr. Natalia Usurelu</i>
DATE:	<i>03.05.2022</i>
EBF	
REF: 10535146	REVISION: AB
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential  $\pm 1/16$ " (1.6mm) tolerance.

Single Sheet 903 Lot W201  
3" x 5" ( $\pm 1/16$ ") - 76.2mm x 127mm  
Prints Bio Black 586 Ink  
Circle size: 9mm ID