

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Eastern Business Forms Inc.  
530 Old Sulphur Springs Road  
Greenville  
South Carolina  
29607  
USA

Holds Certificate No:

**FM 618733**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture, assembly and distribution of paper based specimen receptacles.

For and on behalf of BSI:

  
\_\_\_\_\_  
Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2014-12-05

Latest Revision Date: 2017-11-09

Effective Date: 2017-12-05

Expiry Date: 2020-12-04

Page: 1 of 1



...making excellence a habit.™



To whom it may concern,

The EBF 903 Collection Paper is sold as a CE marked "In-Vitro Diagnostic" device in Europe in compliance with the EU 98/79/EC IVD Directive.

With regards to the IVD Directive, EBF has conducted a Conformity Assessment of the EBF 903 Collection Paper and CE marked the device accordingly.

Therefore, there is no EC Certificate from an accredited Notified Body associated with this device due to EBF's self-declaration of conformity.

EBF can provide the following documentation to support your regulatory requirements:

- Declaration of Conformity
- ISO 13485 Certificate
- Technical Documentation (upon request and possibly through EBF Non-Disclosure Agreement due to proprietary reasons).

Regards,

---

Rick Haines  
Quality/Regulatory Manager  
Eastern Business Forms, Inc.

**EU DECLARATION OF CONFORMITY**

**Manufacturer's name and address:**

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

Hereby declares under our sole responsibility that the product:

Product Trade Name – as it appears on the device(s):	903™
Product Family/Common Name:	903 Filter Paper
Model:	Neonatal and Adult/Child
REF (Catalog/Article No.)	Product is a device customized to suit needs of newborn screening programs or customer needs. Catalog/Article Number(s) are specific to customer product(s).
Serial Number:	Not applicable
Class:	IVD General
GMDN Code:	P 45522

to which this declaration relates, is in conformity and fulfills all the relevant provisions of the in vitro diagnostic medical device directive 98/79/EC (Annex III excluding Section 6) which apply to it.

This conformity is based on the following elements:

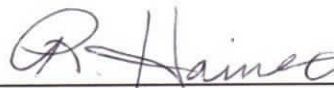
- Technical Documentation F-730-002-A and F-730-002-B, of the product to which this declaration relates
- List of harmonized standards applied for CE Marking

- EN ISO 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2012 Medical devices – Application of risk management to medical device
- CLSI NBS01-A6 Clinical and Laboratory Standards Institute – Blood Collection on Filter Paper for Newborn Screening Programs
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 18113-1:2013 European Norm - In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
- EN ISO 15223-1:2012 European Norm – Medical Devices – Symbols for Use with Medical Device Labels, Labelling and Information to be Supplied

**Date and place of issue:**

11/4/2015 – Greenville, SC (USA)

**Name, position and signature of authorized person:**



Rick Haines  
Quality/Regulatory Manager

**EC Authorized Representative:** CMC, C/ Horacio Lengo N18, CP 29006, Malaga, Spain, +34951214054



QUALITY SYSTEM

**EC-CERTIFICATE**

Directive 98/79/EC

Manufacturer: Labsystems Diagnostics Oy  
Tiilitie 3  
FI-01720 Vantaa  
Finland

Coverage of Certificate: Design, manufacture and final inspection

Product category: Reagents and reagent products for detection and quantification of toxoplasmosis, for diagnosing phenylketonuria, and for determining chlamydia

Valid until: 24<sup>th</sup> April 2019

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. Products covered by the certificate are specified in the attachment(s).

Tampere, 24<sup>th</sup> April 2014

  
Aliisa Siljander




  
Markku Helminen

Certificate no. **VTT-C-11133-02-1172-515-14**



Notified Body no. 0537:  
VTT Expert Services Ltd.  
P.O. Box 345 (Tekniikankatu 1)  
FI-33101 TAMPERE  
FINLAND  
Tel.+358 20 722 111

**Attachment 2 to the Certificate number: VTT-C-11133-02-1172-515-14**

<b>Manufacturer:</b>	Labsystems Diagnostics Oy Tiilitie 3, FI-01720 Vantaa Finland		
<b>Activity and product category:</b>	Design, manufacture and final inspection; reagents and reagent products for diagnosing phenylketonuria		
<b>Products:</b>	The certificate covers the following products:		
	<i>Name</i>	<i>GMDN code</i>	<i>Product code</i>
	- Neonatal Phenylalanine	58960	6199895 6199896 6199897
	- Neonatal Phenylalanine calibrators	53512	6190940
	- Neonatal Phenylalanine controls	53513	6190930
	- NeoMass AAAC	58190	7100100
<b>Date:</b>	Tampere, 11 <sup>th</sup> November 2015		
			
	 Tuomas Toivonen		
	 Mikko Soikkeli		

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 98/79/EC.