bsi.

By Royal Charter

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

Digitally signed by Ceaicovschi Tudor
Date: 2020.12.19 14:57:55 EET
Reason: MoldSign Signature
Location: Moldova

Effective Date: 2017-12-05
Expiry Date: 2020-12-04

...making excellence a habit.™

EASTERN BUSINESS FORMS, INC.

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,

R. Haines

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

VTT EXPERT SERVICES LTD

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:	24th 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, 24th April 2014

VTT EXPERT SERVICES OY VTT EXPERT SERVICES LTD

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

Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3, FI-01720 Vantaa Finland
Activity and product category:	Design, manufacture and final inspection; reagents and reagent products for diagnosing phenylketonuria
Products:	The certificate covers the following products:

Name	*GMDN code*	*Product code*
- Neonatal Phenylalanine	58960	6199895 6199896 6199897
- Neonatal Phenylalanine calibrators	53512	6190940
- Neonatal Phenylalanine controls	53513	6190930
- NeoMass AAAC	58190	7100100

Date:	Tampere, 11th November 2015

VTT EXPERT SERVICES OY
VTT EXPERT SERVICES LTD

Tuomas Toivonen

Mikko Soikkeli

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

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