



## Declaration of Conformity

**LEGAL MANUFACTURER:** Siemens Healthcare Diagnostics Inc.  
Tarrytown, New York 10591-5097  
USA

**PLACE OF MANUFACTURE:** Kimball Electronics (Wales) Limited  
Bridgend Industrial Estate  
Western Avenue  
Bridgend CF31 3TY  
South Wales  
UK

**PRODUCT:** Visual Strips

**PRODUCT CATEGORY:** See attachment 1

**CLASSIFICATION:** Self Declaration

**CONFORMITY ASSESSMENT ROUTE:** ANNEX III Applied

**STANDARDS APPLIED:** ENISO13485:2003 – Quality System for Medical Devices

**DOCUMENT MANAGEMENT SYSTEM No:** 44-35-02 A  
**REV:** 3.0

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Siemens Healthcare Diagnostics Inc.  
Norwood, Massachusetts, USA

  
\_\_\_\_\_  
Noor Malki Date  
Sr. Manager – Regulatory Affairs - POC 11/20/2008

## Declaration of Conformity

		Attachment 1
REF (BAN)	Product Code	Description
00515653	A2425B50	Hematest Reagent Tablets 50's
03783489	A2292C52	Multistix 10 SG Latin (25)
05328339	A2300A29	Multistix 10 SG Nordic
03536597	A2300C51	Multistix 10 SG Europe
00718686	A2300C52	Multistix 10 SG Latin (100)
04200746	A2304C51	Multistix 8 SG Europe (50)
05258055	A2304D29	Multistix 8 SG Nordic (100)
08646323	A2087A52	Microalbustix
09159477	A2289A52	Multistix 8 SG Latin
01211267	A2305D29	Multistix 7 Nordic
07900226	A2740C51	N-Multistix SG Europe
07771019	A2740C52	N-Multistix SG Latin
08259974	A2810C51	Labstix Europe
02827164	A2810C52	Labstix Latin
04581138	A2810F29	Labstix Nordic
05205326	A2857C51	Uristix Europe
01037046	A2857C52	Uristix Latin
04010718	A2857E29	Uristix Nordic
06562467	A2877C51	Hema-Combistix Europe
02924704	A2083B51	Clintek Microalbumin Europe
03330964	A2083B29	Clintek Microalbumin Nordic
03378738	A2083A52	Clintek Microalbumin Portugal
05798300	A2330B50	Multistix 10 Visual
09565653	A1564A36	Multistix Pro 11
04960872	A2087B51	Microalbustix
04624902	A2283J01	Multistix GP UK/Spain
03570159	A2291C18	Multistix 10 SG Germany
02156642	A2300B21	Multistix 10 SG
03390851	A2300C40	Multistix 10 SG
06565954	A2308A52	Multistix 5
07500392	A2308C29	Multistix 5
03242542	A2308C51	Multistix 5
08955414	A2741B51	Multistix SG
04240977	A2743J01	Labstix SG
07571427	A2815C51	N-Labstix
00828708	A2820C51	Multistix
05441720	A2825C18	N-Neostix
01526748	A2300D18	Multistix 10 SG
		End of List

Siemens Healthcare Diagnostics Inc.  
Norwood, Massachusetts, USA

 11/Jul/2008  
**Noor Malki** Date  
**Sr. Manager – Regulatory Affairs - POC**



## Declaration of Conformity

*Siemens Healthcare Diagnostics Inc. is the new owner/operator for all diagnostics products previously owned/operated by The Diagnostics Division of Bayer HealthCare LLC. During a transition period to update product labeling and customer documentation to indicate Siemens Healthcare Diagnostics Inc. as the legal owner you may continue to receive products identified and labeled as Bayer and/or Siemens Medical Solutions Diagnostics.*

*This Declaration of Conformity is applicable for either the Siemens Healthcare Diagnostics Inc., Siemens Medical Solutions Diagnostics and/or Bayer labeled product."*

**Siemens Healthcare Diagnostics Inc.  
Norwood, Massachusetts, USA**

  
**Noor Malki**                      **Date** 11/Jul/2008  
**Sr. Manager – Regulatory Affairs - POC**