DECLARATION OF CONFORMITY

EC Declaration of Conformity to In Vitro Diagnostic Medical Devices (98/79/EC according to Annex III of the IVDD)

Manufacturer:

Company name : PathCom Systems Corporation
Street : 6759 Sierra Court, Suite B
City : Dublin
Postal Code : 94568
State/County/Province : California
Country : USA

Declares that diagnostic products/reagents/ancillaries listed on the attached Device Schedule, classified as “all other IVD Medical Devices” according to Annex IX rules, conform to the relevant provisions of the EC Council Directive 98/79/EC, Art. 1, and are in accordance with Annex III of the IVDD, as implemented by the European Union's Medical Devices Regulations.

List of diagnostic products

code	description
43965	ImPath 36
45703	IMPATH 15ml Vials with caps
45704	IMPATH 7ml Vials with caps
45869	IMPATH Chamber Pads

List of diagnostic reagents and ancillaries

code	description
44993	IMPATH AP-RED DETECTION KIT
44992	IMPATH AP-RED SUPER SENS.DETECT.KIT
44996	IMPATH ISH DETECTION KIT
44999	IMPATH RETRIEVAL SOLUTION PH 9.0
44998	IMPATH RETRIEVAL SOLUTION PH 6.0
45003	IMPATH WASH BUFFER (20X) 125mL
45002	IMPATH WASH BUFFER (20X) 1L

code	description
44997	IMPATH DS ENZYME
45001	IMPATH ANTIBODY DIL.FOR RTU 125 ML
45000	IMPATH HEMATOXYLIN WITH DAB ENHANCER
45004	IMPATH CHAMBER CLEANING KIT
45702	IMPATH TUBING CLEANING KIT
46119	IMPATH TR ENZYME
46171	IMPATH TR BUFFER
46172	IMPATH TR BLOCK
46173	IMPATH DS BUFFER
46174	IMPATH DS BLOCK
46538	IMPATH DAB OB SUP SENS. DET KIT
46539	IMPATH DAB OB DETECTION KIT
47244	IMPATH DS2
47245	IMPATH TR4

References - *where applicable* - to the relevant harmonized standards used or references to the specifications in relation to which conformity is declared:

- ISO 13485:2003
- IEC 60601-1-2
- EN 61326-1:2006
- EN 55011/A2:2007 FCC Part 15, Subpart B:2009 VCCI V-3/2009.04

- EN 61000-3-2:2006
- EN 61000-3-3:1995 + A1:2001 + A2:2005
- EN 61326-1:2006
- EN 61000-4-2:1995 + A1:1999 + A2:2001
- EN 61000-4-3:2006
- EN 61000-4-4:2004
- EN 61000-4-5:2005

- EN 61000-4-6:2007
- EN 61000-4-8:1993 + A1:2001
- EN 61000-4-11:2004

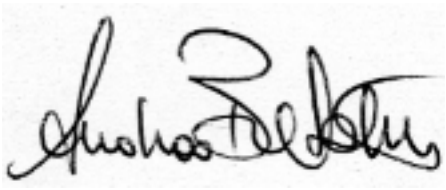
PathCom Systems Corporation agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

PathCom Systems Corporation confirms that no medicinal products/drugs are incorporated in any device covered by the Device Schedules.

PathCom Systems Corporation has appointed

Mr. Andrea Mario Bertolini
Via Gorizia 50
23900, Lecco
Italy

as our EU Authorized Representative.
Signed by the Company's designated representative:
Name: Mr. Andrea Bertolini
Title: Managing Director
Date: 12/23/14



Signed by the Company's legal representative:
Name: Mr. Roy Ye
Title: President
Date: 12/23/14