

EU DECLARATION OF CONFORMITY – EA50

Date: 05/06/2023

This Declaration of Conformity has been issued solely by CellPath Limited (Company Number 01831261) in accordance with the definitions and regulations as described in the **EU Regulation 2017/746 of The European Parliament and of the Council on In-Vitro Diagnostic Medical Devices** and **EU Regulation 1907/2006 of The European Parliament and of the Council on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)**.

General Information

Manufacturer	CellPath Limited
Address of Production Facility	CellPath Ltd (GB-MF-000022744) Unit 80, Mochdre Enterprise Park Newtown, Powys Mid Wales, UK SY16 4LE
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Westervoortsedijk 60, 6827 AT Arnhem The Netherlands
Product Name	Biological stain IVD
Product Description	A chemical agent(s), dye(s) and/or solution(s) intended for the artificial colouration of specific target tissue structures, intra/extracellular elements and/or infectious microorganisms, in a clinical specimen, for their subsequent visualization, examination, identification and/or differentiation.
Product Classification (Classified in accordance with Rule 5 IVDR)	CLASS A

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	BASIC UDI-DI	DESCRIPTION	YEAR OF CE MARKING
RBA-0101-00A	05056256113136	05056256RBA0013R	PAPANICOLAOU EA50M STAIN (MODIFIED) - 1L	2003
RBA-0101-00B	05056256108583	05056256RBA0013R	PAPANICOLAOU EA50M STAIN (MODIFIED) - 1L	2020
RBA-0101-00C	05056256108590	05056256RBA0013R	PAPANICOLAOU EA50M STAIN (MODIFIED) - 1L	2020
RBA-0101-00D	05056256108606	05056256RBA0013R	PAPANICOLAOU EA50M STAIN (MODIFIED) - 1L	2020
RBA-2514-00A	05056256113143	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (VFM) - 2.5L	2003
RBA-2514-00B	05056256108613	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (VFM) - 2.5L	2020
RBA-2514-00C	05056256108620	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (VFM) - 2.5L	2020
RBA-2514-00D	05056256108637	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (VFM) - 2.5L	2020
RBA-4212-00A	05056256113150	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (ORTHO) - 1L	2003
RBA-4212-00B	05056256108552	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (ORTHO) - 1L	2020
RBA-4212-00C	05056256108569	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (ORTHO)- 1L	2020
RBA-4212-00D	05056256108576	05056256RBA0013R	PAPANICOLAOU EA50 STAIN (ORTHO) - 1L	2020

Conformity to the aforementioned regulation is demonstrated by the company's compliance to the following international manufacturing standard:

- **EN ISO 13485:2016** - Medical Devices, Quality Management Systems - Requirements for Regulatory Purposes

Signed on behalf of the Manufacturer. CellPath Limited

Address of Issue CellPath Ltd
 Unit 80, Mochdre Enterprise Park
 Newtown, Powys
 Mid Wales, UK
 SY16 4LE

Date of Issue 05/06/2023

Name of Signatory Alice Parry

Position of Signatory Regulatory Project Manager

Signature 
 Alice Parry (Jun 5, 2023 14:25 GMT+1)

EU - Declaration of Conformity - EA50 v3

Final Audit Report

2023-06-05

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EU DECLARATION OF CONFORMITY – Haematoxylin

Date: 07/06/2023

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General Information

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EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Westervoortsedijk 60, 6827 AT Arnhem The Netherlands
Product Name	Biological stain IVD
Product Description	A chemical agent(s), dye(s) and/or solution(s) intended for the artificial colouration of specific target tissue structures, intra/extracellular elements and/or infectious microorganisms, in a clinical specimen, for their subsequent visualization, examination, identification and/or differentiation.
Product Classification (Classified in accordance with Rule 5 IVDR)	CLASS A

Registered Office:

CellPath Ltd, 3rd Floor 1 Ashley Road,
Altrincham, Cheshire, United Kingdom, WA14 2DT
Reg. No. 01831261

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	BASIC UDI-DI	DESCRIPTION	YEAR OF CE MARKING
RBA-2524-00A	05056256113204	05056256RBA0023T	VFM HAEMATOXYLIN STAIN (STABILISED) - 2.5L	2003
RBA-4201-00A	05056256113198	05056256RBA0023T	HAEMATOXYLIN 'Z' STAIN - 1L	2003
RBA-4205-00A	05056256113167	05056256RBA0023T	VFM HARRIS HAEMATOXYLIN STAIN (ACIDIFIED) - 5L	2003
RBA-4213-00A	05056256113174	05056256RBA0023T	HARRIS HAEMATOXYLIN STAIN (ORTHO) - 1L	2003
RBA-2506-00A	05056256108996	05056256RBA0023T	VFM HARRIS HAEMATOXYLIN STAIN (ACIDIFIED) - 2.5L	2020

Conformity to the aforementioned regulation is demonstrated by the company's compliance to the following international manufacturing standard:

- **EN ISO 13485:2016** - Medical Devices, Quality Management Systems - Requirements for Regulatory Purposes

Signed on behalf of the Manufacturer. CellPath Limited

Address of Issue CellPath Ltd
 Unit 80, Mochdre Enterprise Park
 Newtown, Powys
 Mid Wales, UK
 SY16 4LE

Date of Issue 07/06/2023

Name of Signatory Alice Parry

Position of Signatory Regulatory Project Manager

Signature Alice Parry
 Alice Parry (Jun 8, 2023 08:40 GMT+1)

EU - Declaration of Conformity - Haematoxylin v3

Final Audit Report

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EU DECLARATION OF CONFORMITY – OG6

Date: 06/06/2023

This Declaration of Conformity has been issued solely by CellPath Limited (Company Number 01831261) in accordance with the definitions and regulations as described in the **EU Regulation 2017/746** of The European Parliament and of the Council on In-Vitro Diagnostic Medical Devices and **EU Regulation 1907/2006 of The European Parliament and of the Council on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)**.

General Information

Manufacturer	CellPath Limited
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EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Westervoortsedijk 60, 6827 AT Arnhem The Netherlands
Product Name	Biological stain IVD
Product Description	A chemical agent(s), dye(s) and/or solution(s) intended for the artificial colouration of specific target tissue structures, intra/extracellular elements and/or infectious microorganisms, in a clinical specimen, for their subsequent visualization, examination, identification and/or differentiation.
Product Classification <i>(Classified in accordance with Rule 5 IVDR)</i>	CLASS A

DEVICE(S) INFORMATION

PART NUMBER	GTIN	BASIC UDI-DI	DESCRIPTION	YEAR OF CE MARKING
RBA-2504-00A	05056256113211	05056256RBA0033V	VFM PAPANICOLAOU STAIN OG6 - 2.5L	2006
RBA-2504-00B	05056256110135	05056256RBA0033V	VFM PAPANICOLAOU STAIN OG6 - 2.5L	2020
RBA-2504-00C	05056256110142	05056256RBA0033V	VFM PAPANICOLAOU STAIN OG6 - 2.5L	2020
RBA-2504-00D	05056256110159	05056256RBA0033V	VFM PAPANICOLAOU STAIN OG6 - 2.5L	2020
RBA-4211-00A	05056256113228	05056256RBA0033V	PAPANICOLAOU OG6 STAIN (ORTHO) - 1L	2005
RBA-4211-00B	05056256108644	05056256RBA0033V	PAPANICOLAOU OG6 STAIN (ORTHO) - 1L	2020
RBA-4211-00C	05056256108651	05056256RBA0033V	PAPANICOLAOU OG6 STAIN (ORTHO) - 1L	2020
RBA-4211-00D	05056256108668	05056256RBA0033V	PAPANICOLAOU OG6 STAIN (ORTHO) - 1L	2020

Conformity to the aforementioned regulation is demonstrated by the company's compliance to the following international manufacturing standard:

- **EN ISO 13485:2016** - Medical Devices, Quality Management Systems - Requirements for Regulatory Purposes

Signed on behalf of the Manufacturer. CellPath Limited

Address of Issue CellPath Ltd
 Unit 80, Mochdre Enterprise Park
 Newtown, Powys
 Mid Wales, UK
 SY16 4LE

Date of Issue 06/06/2023

Name of Signatory Alice Parry

Position of Signatory Regulatory Project Manager

Signature Alice Parry
 Alice Parry (Jun 6, 2023 15:40 GMT+1)

EU - Declaration of Conformity (REACH) - OG6 v3

Final Audit Report

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