

EU DECLARATION OF CONFORMITY – Cytifixx

Date: 09/08/2021

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 **Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH)**.


General Information

Manufacturer	CellPath Limited
Address of Production Facility	CellPath Ltd Unit 80, Mochdre Enterprise Park Newtown Powys Mid Wales, UK SY16 4LE
Authorized Representative	EMERGO EUROPE (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Cytology fixative solution IVD
Product Description	An alcohol-based solution intended to be used as a fixative for a cytology specimen obtained directly from a patient, or processing of a clinical specimen, for subsequent preservation, transportation and/or in vitro diagnostic analysis.
Product Classification <i>(Classified in accordance with EU Regulation 2017/746)</i>	CLASS A

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
NHB-0100-01A	05056256113488	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 50ml - CYTOLOGICAL FIXATIVE	2006
NHB-0101-01A	05056256113495	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 150ml - CYTOLOGICAL FIXATIVE	2005
NHB-0200-01A	05056256113501	05056256NHB0014E	CYTOFIXX DROPPER - 50ml - CYTOLOGICAL FIXATIVE	2005
NHB-0201-01A	05056256113518	05056256NHB0014E	CYTOFIXX-II DROPPER - 50ml - CYTOLOGICAL FIXATIVE	2006
NHB-0100-01B	05056256108484	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 50ml - CYTOLOGICAL FIXATIVE	2020
NHB-0101-01B	05056256108514	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 150ml - CYTOLOGICAL FIXATIVE	2021
NHB-0100-01C	05056256108491	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 50ml - CYTOLOGICAL FIXATIVE	2020
NHB-0101-01C	05056256108521	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 150ml - CYTOLOGICAL FIXATIVE	2020
NHB-0100-01D	05056256108507	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 50ml - CYTOLOGICAL FIXATIVE	2020
NHB-0101-01D	05056256108538	05056256NHB0014E	CYTOFIXX PUMP SPRAY - 150ml - CYTOLOGICAL FIXATIVE	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	09/08/2021
Name of Signatory	Hannah Moore
Position of Signatory	Product Manager
Signature	 <small>H Moore (Aug 9, 2021 09:03 GMT+1)</small>

Registered Office:

CellPath Ltd, 80 Mochdre Enterprise Park,
Newtown, Powys, SY16 4LE Mid Wales, UK
Registration Number: 01831261