

EU DECLARATION OF CONFORMITY – Cytotfixx

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 CLASS A
(Classified in accordance with EU
Regulation 2017/746)

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

H Moore
H Moore (Aug 9, 2021 09:03 GMT+1)

Registered Office:

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