

EU DECLARATION OF CONFORMITY – CYTOLOGY FUNNELS

Date: 02/09/2022

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**.

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 Authorized Representative	Emergo Europe (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Cytological centrifuge funnel
Product Description	A small, tapered receptacle designed to be fitted into a cytological centrifuge/sample concentrator and intended to contain and help concentrate clinical specimen suspension cells into thin-layer preparations by depositing them directly onto a microscope slide during centrifugation for subsequent examination. It is in the form of a conical-shaped plastic receptacle; some types have a slot for inserting a microscope slide. This is a single-use device.
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
NND-4000-09A	05056256116069	05056256NND0016W	CYTOLOGY FUNNEL SINGLE 0.4ml - DISPOSABLE (INDIV WRAP)	2006
NND-4000-10A	05056256116090	05056256NND0016W	CYTOLOGY FUNNEL SINGLE 0.4ml - DISPOSABLE (BULK)	2006
NND-4000-10B	05056256100716	05056256NND0016W	CYTOLOGY FUNNEL SINGLE 0.4ml - DISPOSABLE (INDIV WRAP)	2016
NND-4001-09A	05056256110302	05056256NND0016W	CYTOLOGY FUNNEL SINGLE 0.4ml-DISPOSABLE (BROWN) (INDIV WRAP)	2010
NND-4001-10A	05056256100723	05056256NND0016W	CYTOLOGY FUNNEL SINGLE 0.4ml-DISP (BROWN) (IND WRAP) (EF)	2016
NND-4004-08A	05056256110296	05056256NND0016W	CYTOLOGY FUNNEL DOUBLE 0.25ml - DISPOSABLE (INDIV WRAP)	2006
NND-4004-10A	05056256116106	05056256NND0016W	CYTOLOGY FUNNEL DOUBLE 0.25ml - DISPOSABLE (BULK)	2006
NND-4004-12A	05056256100730	05056256NND0016W	CYTOLOGY FUNNEL DOUBLE 0.25ml - DISPOSABLE (INDIV WRAP)	2016
NND-4008-50A	05056256116076	05056256NND0016W	CYTOLOGY FUNNEL CLIP - STAINLESS STEEL	2006
NND-4009-09A	05056256116083	05056256NND0016W	CYTOLOGY FUNNEL CLIP - DISPOSABLE	2010
NND-4009-10A	05056256100747	05056256NND0016W	CYTOLOGY FUNNEL CLIP - DISPOSABLE	2016

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 02/09/2022

Name of Signatory Alice Parry

Position of Signatory Regulatory Project Manager

Signature 
Alice Parry (Sep 2, 2022 09:55 GMT+1)

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Final Audit Report

2022-09-02

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