CellPath
INNOVATION IN CELLULAR PATHOLOGY

Instructions for Use Approval Checklist

Product/Product Group: CellSafe + Biopsy Capsule

Version: V10

Synergy no: 00·128·965

Required elements:

Name of device	☑	Warnings/precautions*** N/A	☐
Part number	☑	Requirements for special facilities e.g. clean room N/A	☐
Name, registered tradename/trademark, address of manufacturer	☑	Conditions for collection, handling and preparation of specimen	☑
Telephone no, fax no, website address	☑	Preparation of device before use e.g. final assemble, calibration N/A	☐
Date of issue of IFU and revision no	☑	Proper installation of device**** N/A	☐
Intended use*	☑	Quality control procedures	☑
Indication the device is IVD/MD	☑	Assay procedure and/or analytical performance characteristics N/A	☐
Intended user	☑	If device is single use, note risk involved with reuse	☑
Test Principle (where applicable)	☑	Safe disposal information****	☑
Calibrator or controls** (where applicable) N/A	☐	Notice about serious incidents/vigilance reporting	☑
Description of reagents (where applicable) N/A	☐	If device is a kit, lit of individual items if available as separate devices N/A	☐
List of materials (where applicable)	☑	Software information (for electrical devices)	☐ N/A
Any device to be used in combination	☑	Contra indications/side effects (MD's only)	☐ N/A
Shelf life N/A	☐	Clinical performance characteristics (Annex I section 9.1)	☑
Storage/handling conditions	☑	If device is for self testing please see Annex I 20.4.2	
Sterile state/sterilisation method N/A	☐		

Approval:

MARKETING	REGULATORY	MANAGING DIRECTORS
☐APPROVED ☐AMEND&REPROOF	☑APPROVED ☐AMEND&REPROOF	☑APPROVED ☐AMEND&REPROOF
Sign:	**Sign:** AROyle AOxford	**Sign:** P. WEBSTER.
Date: 8/10/18	**Date:** 8/10/2018	**Date:** 8/10/18.