

EU DECLARATION OF CONFORMITY – MACRO KNIVES

Date: 21/07/2021

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**.

General Information

Manufacturer	CellPath Limited
Address of Production Facility	CellPath Ltd Unit 80, Mochdre Enterprise Park Newtown, Powys Mid Wales, UK SY16 4LE
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Histology/pathology tissue knife IVD
Product Description	A hand-held manual cutting instrument intended to be used to cut and/or slice human tissues in a histopathology laboratory for subsequent in vitro diagnostic investigation. It is typically in the form of a sharp, thin and broad stainless-steel blade with a proximal handle made of synthetic polymer (e.g., plastic) or wooden material; it may be a one-piece or modular device. This is a reusable device.
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
CAA-0401-01A	05060470560492	05060470CAA001Q7	4 INCH (100mm) CARTILAGE KNIFE	2003
CAA-0601-01A	05060470560508	05060470CAA001Q7	6 INCH (150mm) TRIMMING KNIFE	2003
CAA-0801-01A	05060470560515	05060470CAA001Q7	8 INCH (200mm) MACRO KNIFE	2003
CAA-1001-01A	05060470560522	05060470CAA001Q7	10 INCH (250mm) LUNG KNIFE	2003
CAA-1201-01A	05060470560539	05060470CAA001Q7	12 INCH (300mm) BRAIN KNIFE	2003
CAA-9901-01A	05060470560546	05060470CAA001Q7	ASSORTED KNIVES (2 X EACH SIZE)	2003

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 21/07/2021

Name of Signatory Paul Webber

Position of Signatory Joint Managing Director

Signature Paul Webber
Paul Webber (Jul 21, 2021 16:40 GMT+1)