

EU DECLARATION OF CONFORMITY – STAINLESS STEEL BASE MOULDS

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	Tissue embedding mould IVD, reusable
Product Description	A metal container of square or rectangular shape intended to be used to embed tissue specimens into an embedding medium (e.g., paraffin wax) to form a solid block, which is subsequently cut into thin sections for processing and analysis of the tissue specimen. It is typically made of stainless steel. This is a reusable device.
Product Classification <i>(Classified in accordance with EU Regulation 2017/746)</i>	CLASS A

Registered Office:

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

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
GBB-0714-05A	05060470564766	05060470GBZ001XM	STAINLESS STEEL BASE MOULD 7x7x5mm	2003
GBB-1014-05A	05060470564773	05060470GBZ001XM	STAINLESS STEEL BASE MOULD 10x24x5mm	2005
GBB-1414-05A	05060470564780	05060470GBZ001XM	STAINLESS STEEL BASE MOULD 14x24x5mm	2005
GBB-1514-05A	05060470567019	05060470GBZ001XM	STAINLESS STEEL BASE MOULD 15x15x5mm	2016
GBB-2414-05A	05060470564797	05060470GBZ001XM	STAINLESS STEEL BASE MOULD 24x24x5mm	2003
GBB-3014-05A	05060470564803	05060470GBZ001XM	STAINLESS STEEL BASE MOULD 30x24x9mm	2003
GBB-3714-05A	05060470564810	05060470GBZ001XM	STAINLESS STEEL BASE MOULD 37x24x9mm	2003
GBC-3614-05A	05060470564827	05060470GBZ001XM	STAINLESS STEEL SUPA MEGA BASE MOULD 36x36x10mm	2005
GBC-6014-05A	05060470564834	05060470GBZ001XM	STAINLESS STEEL SUPA MEGA BASE MOULD 60x45x15mm	2005
GBC-6014-05B	05060470564841	05060470GBZ001XM	STAINLESS STEEL SUPA MEGA SLIM BASE MOULD 60x45x8mm	2011
GBC-6014-05C	05060470564858	05060470GBZ001XM	STAINLESS STEEL SUPA MEGA MOTHER SHIP BASE MOULD 60x45x8mm	2011

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 11:53 GMT+1)