CellPath Ltd
80 Mochdre Enterprise Park,
Newtown, Powys,
SY16 4LE Mid Wales, UK

Tel: +44 (0) 1686 611 333
Fax: +44 (0) 1686 622 946
Email: sales@cellpath.com
Website: www.cellpath.com

EU DECLARATION OF CONFORMITY – DECALCIFIERS

Date: 06/08/2021

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	Decalcifying solution IVD
Product Description	A solution intended to be used as a decalcifying agent in the processing of clinical specimens and biological tissues for subsequent in vitro diagnostic analysis. It is typically in the form of an inorganic acid [e.g., hydrochloric acid (HCl)], organic acid [e.g., formic acid (CH2O2)] or a chelating agent [e.g., ethylenediaminetetraacetic acid (EDTA)].
Product Classification *(Classified in accordance with EU Regulation 2017/746)*	Class A

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DEVICE(S) INFORMATION				
PART NUMBER	**GTIN**	**UDI-DI**	**DESCRIPTION**	**YEAR OF CE MARKING**
EAA-0200-00A	05056256114416	05056256EAA002W4	RDC (RAPID DECALCIFIER) - 1L	2003
EAA-0200-00B	05056256110760	05056256EAA002W4	RDC (RAPID DECALCIFIER) - 1L	2020
EAA-0200-00C	05056256111057	05056256EAA002W4	RDC (RAPID DECALCIFIER) - 1L	2020
EAA-0200-00D	05056256111064	05056256EAA002W4	RDC (RAPID DECALCIFIER) - 1L	2020
EAA-1000-00A	05056256114423	05056256EAA002W4	RDF (MILD DECALCIFIER) - 1L	2003
EAA-1000-00B	05056256108859	05056256EAA002W4	RDF (MILD DECALCIFIER) - 1L	2020
EAA-1000-00C	05056256108866	05056256EAA002W4	RDF (MILD DECALCIFIER) - 1L	2020
EAA-1000-00D	05056256108873	05056256EAA002W4	RDF (MILD DECALCIFIER) - 1L	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	06/08/2021
Name of Signatory	Hannah Moore
Position of Signatory	Product Manager
Signature	H Moore H Moore (Aug 6, 2021 16:06 GMT+1)

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