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

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

EU DECLARATION OF CONFORMITY – CELLSOFT

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** 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
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Nail tissue softening solution IVD
Product Description	A solution [e.g., cetyltrimethylammonium chloride (CTAC)] intended to be used to soften nail tissue and prevent tissue splitting/tearing to facilitate the microtomy of nail biopsies.
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-1500-25A	05056256113112	05056256EAA001W2	CELLSOFT - 4 x 125ml	2009
EAA-1500-25C	05056256107241	05056256EAA001W2	CELLSOFT - 4 x 125ml	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 21/07/2021

Name of Signatory Paul Webber

Position of Signatory Joint Managing Director

Signature Paul Webber
Paul Webber (Jul 21, 2021 16:42 GMT+1)