R&D systems
by biotechne

Doc #: W-COC-0007
Revision: A

EC Declaration of Conformity

Manufacturer Name:	Cyvek, Inc.
Manufacturer Address:	5 Technology Drive Wallingford, CT 06492 USA
Manufacturer SRN: (Single Registration Number)	US-MF-000049483
EU Authorized Representative:	MedEnvoy Global BV Prinses Margrietplantsoen 33, Suite 123 2595 AM The Hague The Netherlands
Product Name:	Ella
Product Catalogue Number(s) / Code(s)	REF 600-100-CE
Basic UDI-DI	860014200310001390 01CEYD
Classification	Class A non-sterile, Rule 5(b)
Intended Purpose	The Ella Instrument is a non-automated instrument intended for in vitro diagnostic use with a supported Ella IVD Assay to perform immunoassay diagnostics. The Ella Instrument sequences the processing of samples, reagents and wash buffers, and measures and sorts fluorescence signals, using a supported Ella IVD Assay Kit. The Ella Instrument is intended for use by trained laboratory personnel.

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Common Specifications / Standards Applied	ISO 13485:2016
	IEC 61010-1:2010 / AMD1:2016
	IEC 61326:2021
	EN ISO 14971:2019
	IEC 60825-1:2014
	IEC 62304:2006/A1:2015
	IEC 62366-1:2015
Directives	EC 1907 / 2006
	2011 / 65 / EU 2015 / 863 / EU

This declaration of conformity is issued under the sole responsibility of Cyvek, Inc. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746 for medical devices. This declaration is supported by the Cyvek Inc. Quality Management System's certification to ISO 13485:2016.

All supporting documentation is retained by the manufacturer.

Roberto L. M—

Roberto Muñoz
Director, Quality Assurance

Wallingford, Connecticut, U.S.A

2026 06 05 (YYYY-MM-DD)

Place and date of Issue