EU DECLARATION OF CONFORMITY

In accordance with ISO 17050-1:2010

Manufacturer:	**Bee Robotics Ltd** 32-33 Cibyn Industrial Estate Caernarfon, Gwynedd LL55 2BD N.Wales UK
Manufacturer SRN	GB-MF-000023998
EU Authorised Representative:	**CS Lifesciences Europe Ltd** The Black Church St. Mary's Place Dublin 7 D07 P4AX Ireland eurep@cslifesciences.com
EU Authorised Representative SRN	IE-AR-000004113
Product Name / Trade Name:	**RoboBlot**
Product Type:	Automated liquid handling instrument
Intended Use:	The RoboBlot is a fully automated standalone Class A in vitro diagnostics instrument used for processing up to 50 samples. The RoboBlot detects the samples using a barcode reader, pipettes all reagents, performs washing of the membranes and transfers a raw image of the developed membranes to a third party interpretation software. The RoboBlot allows for full automation and quantitative determination of strip-based assays using human serum. The assays include (but not limited to) testing for: - Lyme disease - HIV - HPV - Toxoplasma The RoboBlot is suitable for processing samples of all groups of people. It is to be used by trained personnel with samples and reagents (diagnostics kit) that are appropriate for the RoboBlot. The Product is intended for professional use.
Risk Class:	Class A
Catalogue Number:	RB01
Basic UDI:	506096943RB01AQ
GMDN Code:	56724 – Multichannel immunoassay analyser IVD, automated
Product first placed on the market:	2017
Serial number(s):	*tbc*

This Declaration of Conformity is issued under the sole responsibility of Bee Robotics.

We hereby declare that the device(s) mentioned above comply with the following European directives and standards including compliance with the related Essential Requirements and General Safety Performance Requirements.

Any unauthorised changes or modifications made to the device will invalidate the Declaration of Conformance

Directives:
98/79/EC In Vitro Diagnostic Medical Device Directive
EU 2017/746 In Vitro Diagnostic Medical Device Regulation
2014/35/EU Low Voltage Directive
2014/30/EU Electromagnetic Compatibility (EMC) Directive
2011/65/EU + 2015/863 RoHS Directive
1907/2006 + 2020/878 REACH Directive

Standards:
EN 61326-1:2013 and EN 61326-2-6:2013
EN 61010-1:2010, EN 61010-2-010:2014 and EN 61010-2-101:2015
EN ISO 14971:2019

MET Certification:
UL/CSA 61010-1,2012 and UL/CSA 61010-2-010
UL 61010-2-101 2nd Ed and CSA 61010-2-101:15
Listing number E114453

Classification:	**98/79/EC In Vitro Diagnostic Medical Device Directive** - General IVDs **EU 2017/746 In Vitro Diagnostic Medical Device Regulation** - Rule 5
Conformity Assessment Procedure:	**98/79/EC In Vitro Diagnostic Medical Device Directive** - Annex III (1 to 5) **EU 2017/746 In Vitro Diagnostic Medical Device Regulation** - Annex IV (1-10)
Signed on behalf of Bee Robotics:	
Position:	Managing Director
Date:	25th August 2022
Signing Location	**Bee Robotics Ltd** Unit 32/33 Cibyn Industrial Estate Caernarfon, Gwynedd, LL55 2BD N.Wales UK