# EU DECLARATION OF CONFORMITY

In accordance with ISO 17050-1:2010

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| **Manufacturer:** | **Bee Robotics Ltd**<br>32-33 Cibyn Industrial Estate<br>Caernarfon, Gwynedd<br>LL55 2BD<br>N.Wales<br>UK |
| **Manufacturer SRN** | GB-MF-000023998 |
| **EU Authorised Representative:** | **CS Lifesciences Europe Ltd**<br>The Black Church<br>St. Mary's Place<br>Dublin 7<br>D07 P4AX<br>Ireland<br>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.<br><br>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:<br>- Lyme disease<br>- HIV<br>- HPV<br>- Toxoplasma<br><br>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.<br>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

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