**Hamamatsu Lateral Flow Reader Survey (Jan 2024)**

**To our valued customers: we recognize that Hamamatsu Lateral Flow Reader may be used as part of a medical device. Hamamatsu does not have, nor will obtain, any medical device clearances or approvals. All regulatory filings and compliance are fully your company’s responsibility as the medical device manufacturer. To support your needs including customization requirements, please fill out the survey below, sign and return it to us. Then we will confirm the business relationship your company intends to establish with Hamamatsu can be supported.**

**1. Company Profile**

 a. ( ) Our company designs and/or manufacturers medical devices and has ISO13485 or an equivalent quality management system as approved by the regulating authority. => Please provide a copy of the certificate or supporting evidence of your QMS

 b. ( ) Our company designs and/or manufactures medical devices but does not yet have an established quality management system such as ISO13485. => Please declare when you will establish ISO13485 or an equivalent QMS in an official letter with your signature.

 c. ( ) Our company designs and/or manufactures medical devices in countries where ISO13485 or an equivalent quality management system is not required. => Please declare to make business with Hamamatsu exclusively in the specified non-regulated countries.

 d. ( ) Our company designs and/or manufactures medical devices for other applications. Example: Veterinary Use

 e. ( ) Our company is an end user or research organization only.

**2. \* Medical Device Certification:**

 We have already obtained or plan to obtain medical certification by the regulatory organization such as FDA, MDR CE, UKCA or MHLW for our integrated diagnostic system Check One: **Yes** or **No**  . (Medical device applications only)

**Please attach a copy of your medical device certification(s) for all regulated countries.**

**3. Customer Overview**

|  |  |
| --- | --- |
| Company Name |  |
| Address |  |
| Business Contact Info(name, phone & email) |  |

**4. Purpose of use (Check all that apply)**

|  |  |
| --- | --- |
| * Internal use
 | * Development of reagents　□ Quality control of reagents

□　Other ( 　 )  |
| * Launching new business

(OEM Requirements) | * Development of new original reader instrument

□　Promote business of reader and reagents□ Other ( ) |
| Potential Qty |  |
| Target Price |  |
| Schedule |  |
| □　Other | ( ) |

**5. Measurement item of reagent (if possible)**

|  |
| --- |
|  |

**6. Type of reagent (Color line or fluorescence line)**

|  |
| --- |
| * Color line
 |
|  | Color of lines | * Red □ Blue
* Other ( )
 |
| * Fluorescence line
 |
|  | Label | * Eu □ FITC
* Other ( )
 |
| Excitation　light wavelength (nm) |  |
| Fluorescence wavelength (nm) |  |

**7. Configuration and Dimension of reagent kit (please provide a drawing)**

|  |
| --- |
|  |

**8. Customization Requirements**

|  |
| --- |
|  |

**9. Other comments or requests, please describe in the space below.**

|  |
| --- |
|  |

**Hamamatsu Salesperson: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**