Vista Laboratories, Inc.
1261 Puerta Del Sol
San Clemente, CA 92673

Phone: (949) 393-1123
Web: www.vista-compliance.com
Email: info@vista-compliance.com

EU-Type Examination Application (EMC Directive)

1 **Manufacturer** (Person who places it on the market under own trade name)	
Name:	Phone Number and Email:
Address:	Contact Name & Title:

2 **Authorized Representative** (Only required if application is submitted by a representative of the manufacturer)	
Name:	Phone Number and Email:
Address:	Contact Name & Title:
Note: The delegation of tasks from the manufacturer to the authorized representative must be explicitly in writing. An authorization letter from the manufacturer must submitted. The authorized representative must be established inside the Union.	

3 **Client Information** (Organization submitting this form to us)	
Name:	Phone Number and Email:
Address:	Contact Name & Title:

4 **Product Description**	
Brand/Trademark Name:	Model/Type Designation:
Product Description (Briefly in 8-10 words):	
Software version:	
Hardware version:	
Description of use:	

5 **Application Technical File** (To be completed internally by Vista)	
File Identification Number :	
Company Name :	
Applicant Address :	
Issue Date :	
Application type :	☐ New examination ☐ Modification to existing EU-Type examination

6 **Essential Requirements to be Assessed**
Directive: EMCD (2014/30/EU) Annex III (Module B)
Aspect of Essential Requirements ☐ EMC Emissions (Electromagnetic disturbance generated) ☐ EMC Immunity (Immunity to the electromagnetic disturbance)

Vista Laboratories, Inc.
1261 Puerta Del Sol
San Clemente, CA 92673

Phone: (949) 393-1123
Web: www.vista-compliance.com
Email: info@vista-compliance.com

7 Technical File Exhibits		
Item	Exhibit Description	Exhibit Name/Number (or file name)
1.	Copy of declaration of conformity :	
2.	Agent/Representative authorization letter from Manufacturer (if application is filed by someone other than Manufacturer)	
3.	User information and installation instructions (user manual, etc.)	
4.	Conceptual design and manufacturing drawings of components:	
5.	Photographs or illustrations showing external features, marking and internal layout	
6.	Descriptions/explanations for understanding drawings/schemes of operation of the apparatus	
7.	Results of design calculations made, examinations carried out :	
8.	Test reports :	

8 Essential Requirements and Standards Applied				
Aspect	**Standard Number** (include version and/or year) When harmonized standards have not been applied, manufacturer must provide descriptions of solutions adopted to meet the essential requirements in Directive 2014/30/EU and list of technical specifications applied	**Harmonized Standard Applied in Full**	**Harmonized Standard Applied in Part**	**Harmonized Standard Not Applied**
Emissions :		☐	☐	☐
Immunity :		☐	☐	☐

I declare that, I will:

- Always comply with the relevant provisions of the EU Directives;
- Make claims regarding EU-Type Examination only in respect to the scope for which the certificate has been issued;
- Not use its EU-Type Examination Certificate in such a manner as to bring the Notified Body into disrepute and does not make any statement regarding its certificate on which the Notified Body may consider misleading or unauthorized;
- Discontinue its use of all advertising matter that contains any reference to EU-Type Examination and returns any EU-Type Examination documents as required by the Notified Body upon suspension or cancellation of certificate;
- Reproduce copies of the EU-Type Examination documents, provided to others, in their entirety or as specified in the EU-Type Examination scheme;
- Ensure that reference to its EU-Type Examination in communication media such as documents, brochures or advertising, complies with the requirements of the Notified Body;
- Ensure that product markings and references to the EU-Type Examination meet the requirements of EU Directives;

Vista Laboratories, Inc.
1261 Puerta Del Sol
San Clemente, CA 92673

Phone: (949) 393-1123
Web: www.vista-compliance.com
Email: info@vista-compliance.com

- Keep a record of all complaints made known to the supplier relating to a product's compliance with the requirements of the relevant standard and to make these records available to the Notified Body when requested;
- Take and document appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for EU-Type Examination;
- Endeavor to ensure that no certificate or report or any part thereof is used in a misleading manner;
- The manufacturer must notify us of any changes made to this product that might affect the compliance of this device.
- I have established a Technical Documentation as referenced in this application to be presented to the Notified Body to enable assessment of the product conformity with the essential requirements of the EMCD and to be kept at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.
- The same application has not been lodged with any other notified body;
- For product being placed on the market in the EU, I shall inform the notified body that holds the technical documentation relating to the EU-Type Examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate. Failing to maintain compliance with the requirements may result in Notified Body to suspend or withdraw the EU-Type Examination Certificate;
- In the course of the monitoring of conformity following the issue of an EU-Type Examination certificate, if the Notified Body finds that the apparatus no longer complies or the Certificate is expired, I shall provide a reply to the Notified Body, no later than 15 days of the request, with corrective measures. Failing to respond within the required time may result in Notified Body to suspend or withdraw the EU-Type Examination Certificate;
- If I do not take corrective measures or the corrective measures do have the required effect, the Notified Body may restrict, suspend or withdraw the EU-Type Examination certificate, as appropriate.

I consent to the following obligations of the Notified Body:

- a) any refusal, restriction, suspension or withdrawal of a certificate; b) any circumstances affecting the scope of or conditions for notification; c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities; d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting. 1. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same apparatus with relevant information on issues relating to negative and, on request, positive conformity assessment results Annex III (8) Paragraph 1 Each notified body shall inform its notifying authority (NIST) concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted Paragraph 2 Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and upon request, concerning such certificates and/or additions thereto which it has issued. Paragraph 3 The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

Drawn up in (type in location) :	
Date (mm/dd/yyyy) :	
Signature:	
Family/Last Name and First/Given Name:	
Position/Title :	
Manufacturer (Applicant) Name:	