



अखिल भारतीय आयुर्विज्ञान संस्थान ऋषिकेश, उत्तराखण्ड
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RISHIKESH-249203

Form P-3

(To be attached with form P-2 for purchase of Proprietary Articles)

PROPRIETARY ARTICLE CERTIFICATE

It is to certify that **Consumables items for ECIQ Analyser/Vitros 3600** for the department of Transfusion Medicine & Blood Bank as mentioned in Form P-2 may be purchased from **M/s Excel Biosystem Pvt. Ltd.** as to the best of knowledge, **M/s Excel Biosystem Pvt. Ltd.** is the authorize distributor/supplier of the sole manufacturer **M/s Ortho Clinical Diagnostics India Private Limited** of above said equipment.

Further, it is to certify that similar items manufactured by other firm (s) shall not be suitable for our purpose because of below mentioned reasons:

1. The equipment is a closed system, only ortho reagents should be used.

Indenter Signature:

डॉ० आशीष जैन / Dr. Ashish Jain
सह-आचार्य / Associate Professor
चिकित्सा एवं रक्तकोष विभाग
Transfusion Medicine & Blood Bank
एम्स ऋषिकेश / AIIMS, Rishikesh

Indenter Name: Dr. Ashish Jain

Designation: Associate Professor

Department: Transfusion Medicine & Blood Bank

Date: 14-02-2025

Recommendation:

Signature of Head of Department/Section

गिता नेगी
Prof. (Dr.) Gita Negi
आचार्या एवं विभागाध्यक्षा / Professor & Head
रक्तधान चिकित्सा एवं रक्तकोष विभाग
Transfusion Medicine & Blood Bank
एम्स, ऋषिकेश / AIIMS, Rishikesh

Note: The indenter, before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature and is manufactured under patent laws.

Date: 18th March, 2024

Proprietary Certificate

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the below mentioned item is proprietary item of Ortho-Clinical Diagnostics Inc., USA. Below listed product is imported by Ortho Clinical Diagnostics India Private Limited to market and supply it throughout India.

Product Code	Product Description
1922814	VITROS® ECIQ Immunodiagnostic System

VITROS® ECIQ Immunodiagnostic System offers three proprietary technologies:

1. **VITROS® MicroWell Technology**, which maximizes binding capacities with a unique coating process. Enhanced Chemiluminesce Detection Technology is a component of MicroWell Technology that provides wide dynamic ranges and exceptional immunoassay precision and accuracy across multiple disease states.
2. **VITROS® Microsensor Technology**, which utilizes the VITROS MicroSensor™ system to perform automated semi-quantitative sample quality index determinations on serum, plasma, and cerebrospinal fluid samples. The MicroSensor™ feature is intended to assist laboratory personnel in assessing the suitability of a patient sample for use on the VITROS 5600 Integrated System. The optical absorbance from 400-800 nm is automatically read and recorded for each sample. Multi-variant analysis of the spectral data provides estimates of the hemolysis, icterus, and turbidity indices in the sample.
3. **VITROS® Intellicheck® Technology**, which is Integrated Process Control, and offers unique technologies that perform, monitor, and verify diagnostic checks throughout sample processing, assay processing, and reporting results. IntelliReport™, a component of Intellicheck® Technology, reports real-time status of every result, assures the integrity of every result, and serves as an important record for result quality.

प्रोफ. (डॉ.) गीता नेगी
Prof. (Dr.) Gita Negi
आचार्या एवं विभागाध्यक्षा / Professor & Head
रक्तदान चिकित्सा एवं रक्तकोष विभाग
Transfusion Medicine & Blood Bank
एम्स, ऋषिकेश / AIIMS, Rishikesh

To Whom So Ever It May Concern

Date: 14 March 2023

Proprietary Certificate

This is to certify that the below mentioned item is proprietary item of Ortho-Clinical Diagnostics Inc., USA. Below listed product is imported by Ortho Clinical Diagnostics India Private Limited to market and supply it throughout India.

Product Code	Product Description
6802783	VITROS® 3600 Immunodiagnostic System

VITROS® 3600 Immunodiagnostic System offers Three proprietary technologies:

1. **VITROS® MicroWell Technology**, which maximizes binding capacities with a unique coating process. Enhanced Chemiluminesce Detection Technology is a component of MicroWell Technology that provides wide dynamic ranges and exceptional immunoassay precision and accuracy across multiple disease states.
2. **VITROS® Microsensor Technology**, which utilizes the VITROS MicroSensor™ system to perform automated semi-quantitative sample quality index determinations on serum, plasma, and cerebrospinal fluid samples. The MicroSensor™ feature is intended to assist laboratory personnel in assessing the suitability of a patient sample for use on the VITROS 5600 Integrated System. The optical absorbance from 400-800 nm is automatically read and recorded for each sample. Multi-variant analysis of the spectral data provides estimates of the hemolysis, icterus, and turbidity indices in the sample.
3. **VITROS® Intellicheck® Technology**, which is Integrated Process Control, and offers unique technologies that perform, monitor, and verify diagnostic checks throughout sample processing, assay processing, and reporting results. IntelliReport™, a component of Intellicheck® Technology, reports real-time status of every result, assures the integrity of every result, and serves as an important record for result quality.


Ana Parra
(APARRA)

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Parra (APARRA)
Reason: I am approving
this document
Date: 2023.03.14
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Authorized Signatory

14-March2023

Date


प्रोफ. (डॉ.) गीता नेगी
Prof. (Dr.) Gita Negi
आचार्या एवं विभागाध्यक्षा / Professor & Head
रक्तदान चिकित्सा एवं रक्तकोष विभाग
Transfusion Medicine & Blood Bank
एम्स, ऋषिकेश / AIIMS, Rishikesh

Date: 10 July 2023

Proprietary Certificate

TO WHOMSOEVER IT MAY CONCERN

Ortho Clinical Diagnostics, Inc., USA is a legal manufacturer of clinical diagnostics equipment VITROS ECi/ECiQ Immunodiagnostic System/ VITROS 3600 Immunodiagnostic System/ VITROS 5600 Integrated System/ VITROS XT 7600 Integrated System & is proprietary product of Ortho-Clinical Diagnostics, Inc., USA and is exclusively marketed in India by Ortho Clinical Diagnostics India Pvt. Ltd. having its Registered office at 403, Leela Business Park , Andheri Kurla Road , Andheri East ,Mumbai -400059, India.

Below products are proprietary product of Ortho Clinical Diagnostics with manufacturer Ortho Clinical Diagnostics, UK or Ortho Clinical Diagnostics, USA (indicated by *) and can only be used on VITROS ECi/ECiQ Immunodiagnostic System/ VITROS 3600 Immunodiagnostic System/ VITROS 5600 Integrated System/ VITROS XT 7600 Integrated System & no other products can be used on these instrument systems.

Sr. No.	Product Code	Product Description	Pack Size
Reagents			
1	6199922	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	100 wells
2	6199919	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	100 wells
3	6905558	VITROS Immunodiagnostic Products B•R•A•H•M•S PCT Reagent Pack	100 wells
4	6844436	VITROS Immunodiagnostic Products hs Troponin I Reagent Pack	100 Tests
5	1453489	VITROS Immunodiagnostic Products B12 Reagent Pack	100 wells
6	1142561	VITROS Immunodiagnostic Products B12/Folate Reagent Pack 3	200 wells
7	8356636	VITROS Immunodiagnostic Products Ferritin Reagent Pack	100 wells
8	1513266	VITROS Immunodiagnostic Products Folate Reagent Pack	100 wells
9	1896836	VITROS Immunodiagnostic Products CK-MB Reagent Pack	100 wells
10	6801042	VITROS Immunodiagnostic Products Myoglobin Reagent Pack	100 wells
11	6802301	VITROS Immunodiagnostic Products Troponin I ES Reagent Pack	100 wells
12	6801827	VITROS Immunodiagnostic Products CMV IgG Reagent Pack	100 wells
13	6801830	VITROS Immunodiagnostic Products CMV IgM Reagent Pack	100 wells

Sr. No.	Product Code	Product Description	Pack Size
14	1074053	VITROS Immunodiagnostic Products Cortisol Reagent Pack	100 wells
15	1315589	VITROS Immunodiagnostic Products Free T3 Reagent Pack	100 wells
16	1387000	VITROS Immunodiagnostic Products Free T4 Reagent Pack	100 wells
17	8450124	VITROS Immunodiagnostic Products Anti-HAV IgM Reagent Pack	100 Tests
18	6801461	VITROS Immunodiagnostic Products Anti-HAV Total Reagent Pack	100 Tests
19	6802892	VITROS Immunodiagnostic Products Intact PTH Reagent Pack	100 wells
20	6802156	VITROS Immunodiagnostic Products NT-proBNP Reagent Pack	100 wells
21	6800030	VITROS Immunodiagnostic Products NTx Reagent Pack	100 wells
22	1920115	VITROS Immunodiagnostic Products CEA Reagent Pack	100 Wells
23	6800038	VITROS Immunodiagnostic Products CA 125 II Reagent Pack	100 wells
24	6800039	VITROS Immunodiagnostic Products CA 15-3 Reagent Pack	100 wells
25	6800040	VITROS Immunodiagnostic Products CA 19-9 Reagent Pack	100 Wells
26	6842845	VITROS Immunodiagnostic Products Free PSA Reagent Pack	100 wells
27	6842844	VITROS Immunodiagnostic Products Total PSA II Reagent Pack	100 wells
28	1925551	VITROS Immunodiagnostic Products AFP Reagent Pack	100 wells
29	8552630	VITROS Immunodiagnostic Products Estradiol Reagent Pack	100 wells
30	1931922	VITROS Immunodiagnostic Products FSH Reagent Pack	100 wells
31	1350198	VITROS Immunodiagnostic Products LH Reagent Pack	100 wells
32	1938570	VITROS Immunodiagnostic Products Progesterone Reagent Pack	100 wells
33	1849793	VITROS Immunodiagnostic Products Prolactin Reagent Pack	100 wells
34	1435205	VITROS Immunodiagnostic Products Testosterone Reagent Pack	100 wells
35	6802220	VITROS Immunodiagnostic Products Total β -hCG II Reagent Pack	100 wells
36	1484427	VITROS Immunodiagnostic Products Rubella IgM Reagent Pack	100 wells

Sr. No.	Product Code	Product Description	Pack Size
37	8536195	VITROS Immunodiagnostic Products Rubella IgG Reagent Pack	100 wells
38	6842803	VITROS Immunodiagnostic Products Syphilis TPA Reagent Pack	100 wells
39	1322528	VITROS Immunodiagnostic Products Total T3 Reagent Pack	100 wells
40	8744468	VITROS Immunodiagnostic Products Total T4 Reagent Pack	100 wells
41	1912997	VITROS Immunodiagnostic Products TSH Reagent Pack	100 wells
42	8091399	VITROS Immunodiagnostic Products Toxoplasma IgG Reagent Pack	100 wells
43	8669335	VITROS Immunodiagnostic Products Toxoplasma IgM Reagent Pack	100 wells
44	6842894	VITROS Immunodiagnostic Products 25-OH Vitamin D Reagent Pack	100 wells
45	1471481	VITROS Immunodiagnostic Products T3 Uptake Reagent Pack	100 Tests
46	1107804	VITROS Immunodiagnostic Products Red Cell Folate Pack	50 Tests
47	6844411	VITROS Immunodiagnostic Products NephroCheck Test Reagent Pack	100 Tests
48	6844425	VITROS Immunodiagnostic Products Insulin Reagent Pack	100 Tests
49	8496812	VITROS Immunodiagnostic Products Anti-HBc Reagent Pack	100 wells
50	8577413	VITROS Immunodiagnostic Products Anti-HBc IgM Reagent Pack	100 wells
51	8864860	VITROS Immunodiagnostic Products Anti-HBe Reagent Pack	100 wells
52	8211880	VITROS Immunodiagnostic Products HBeAg Reagent Pack	100 wells
53	1787753	VITROS Immunodiagnostic Products Anti-HBs Reagent Pack	100 wells
54	6802131	VITROS Immunodiagnostic Products HBsAg ES Reagent Pack	100 Tests
55	6802133	VITROS Immunodiagnostic Products HBsAg ES Confirmatory Kit	100 wells
56	1318450	VITROS Immunodiagnostic Products Anti-HCV Reagent Pack	100 wells
57	1241850	VITROS Immunodiagnostic Products Anti-HIV 1 + 2 Reagent Pack	100 Tests
58	6842779	VITROS Immunodiagnostic Products HIV Combo Reagent Pack	100 wells

Sr. No.	Product Code	Product Description	Pack Size
59	6844423	VITROS Immunodiagnostic Products C-peptide Reagent Pack	100 Tests
60	6844452	VITROS Immunodiagnostic Products NT-proBNP II Reagent Pack	100 Tests
61	6900446	VITROS Immunodiagnostic Products Anti-HTLV I/II Reagent Pack	100 Test
62	6199971	VITROS Immunodiagnostic Products IL 6 Reagent	100 Test
Calibrator			
Sr. No.	Product Code	Product Description	Pack Size
63	6199923	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator	2 x 1ml
64	6199920	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator	2 x 1ml
65	6905559	VITROS Immunodiagnostic Products B•R•A•H•M•S PCT Calibrators	2 levels/1 ml vials
66	6844437	VITROS Immunodiagnostic Products hs Troponin I Calibrator	3 vials (1 per level)
67	1540525	VITROS Immunodiagnostic Products B12 Calibrators	3 levels/1set
68	1158864	VITROS Immunodiagnostic Products Ferritin Calibrators	3 levels/3 sets freeze dried
69	1311075	VITROS Immunodiagnostic Products Folate Calibrators	3 levels/1set Liquid
70	1286293	VITROS Immunodiagnostic Products CK-MB Calibrators	3 levels/3 sets freeze dried
71	6801043	VITROS Immunodiagnostic Products Myoglobin Calibrators	3 levels/1set
72	6802302	VITROS Immunodiagnostic Products Troponin I ES Calibrators	3levels/1set
73	619 9923	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator	1 Box- 2x 1 ml
74	619 9920	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator	1 Box- 2x 1 ml
75	6801828	VITROS Immunodiagnostic Products CMV IgG Calibrators	2 levels, 1 vial each
76	6801831	VITROS Immunodiagnostic Products CMV IgM Calibrator	1 level
77	1681543	VITROS Immunodiagnostic Products Cortisol Calibrators	3 levels/3 sets freeze dried
78	1112820	VITROS Immunodiagnostic Products Free T3 Calibrators	3 levels/3 sets freeze dried

Sr. No.	Product Code	Product Description	Pack Size
79	1728872	VITROS Immunodiagnostic Products Free T4 Calibrators	3 levels/3 sets freeze dried
80	1372101	VITROS Immunodiagnostic Products Anti-HAV IgM Calibrator	1 level/1 set liquid
81	1421932	VITROS Immunodiagnostic Products HBsAg Calibrators	1 level/ 1 set
82	6801462	VITROS Immunodiagnostic Products Anti-HAV Total Calibrator	1 vial
83	6802893	VITROS Immunodiagnostic Products Intact PTH Calibrators	3 levels/1 set
84	6802157	VITROS Immunodiagnostic Products NT-proBNP Calibrators	3 levels/1 set
85	6800031	VITROS Immunodiagnostic Products NTx Calibrators	3levels/1 set Liquid
86	6800034	VITROS Immunodiagnostic Products CA 125 II Calibrators	3levels/1 set Liquid
87	6800033	VITROS Immunodiagnostic Products CA 15-3 Calibrators	3 levels/1 set Liquid
88	6800035	VITROS Immunodiagnostic Products CA 19-9 Calibrators	3 levels/1 set Liquid
89	1062306	VITROS Immunodiagnostic Products CEA Calibrators	3 levels/1 set Liquid
90	6842847	VITROS Immunodiagnostic Products Free PSA Calibrators	3 levels/1 set Liquid
91	6842849	VITROS Immunodiagnostic Products Total PSA II Calibrators	3 levels/1 set Liquid
92	1515154	VITROS Immunodiagnostic Products AFP Calibrators	3 levels/1set liquid
93	1318930	VITROS Immunodiagnostic Products Estradiol Calibrators	3 levels/1 set freeze dried
94	1901263	VITROS Immunodiagnostic Products FSH Calibrators	2 levels/1 set liquid
95	1090133	VITROS Immunodiagnostic Products LH Calibrators	2 levels/1 set liquid
96	8254898	VITROS Immunodiagnostic Products Progesterone Calibrators	3 sets of 3 Calibrators
97	1113596	VITROS Immunodiagnostic Products Prolactin Calibrators	2 levels/3 sets freeze dried
98	1306026	VITROS Immunodiagnostic Products Testosterone Calibrators	3 levels/1 set liquid
99	6802221	VITROS Immunodiagnostic Products Total β -hCG II Calibrators	2 levels/3 sets freeze dried
100	8017600	VITROS Immunodiagnostic Products Rubella IgM Calibrator	1 level

Sr. No.	Product Code	Product Description	Pack Size
101	8209074	VITROS Immunodiagnostic Products Rubella IgG Calibrators	3 levels, 1 vial each
102	6842804	VITROS Immunodiagnostic Products Syphilis TPA Calibrator	1 level/ 1 set
103	1614965	VITROS Immunodiagnostic Products Total T3 Calibrators	3 levels/I set liquid
104	1393396	VITROS Immunodiagnostic Products Total T4 Calibrators	3 levels/I set liquid
105	1487289	VITROS Immunodiagnostic Products TSH Calibrators	3 levels/1 set liquid
106	8254989	VITROS Immunodiagnostic Products Progesterone Calibrators	2levels/1set liquid
107	1893312	VITROS Immunodiagnostic Products Toxoplasma IgG Calibrators	2 levels, 1 vial each
107	1120492	VITROS Immunodiagnostic Products Toxoplasma IgM Calibrator	1 level
109	6842893	VITROS Immunodiagnostic Products 25-OH Vitamin D Calibrators	3 levels/1 set
110	1209733	VITROS Immunodiagnostic Products T3 Uptake Calibrators	3 sets of each of 2 vials
111	6844412	VITROS Immunodiagnostic Products NephroCheck Test Calibrator	9 vials (3 per level)
112	6844426	VITROS Immunodiagnostic Products Insulin Calibrator	3 vials (1 per level)
113	1256494	VITROS Immunodiagnostic Products Anti-HBc Calibrator	1 level/1 set liquid
114	1100387	VITROS Immunodiagnostic Products Anti-HBc IgM Calibrator	1 level/1 set liquid
115	1523984	VITROS Immunodiagnostic Products Anti-HBe Calibrator	3 levels/3 sets liquid
116	1914498	VITROS Immunodiagnostic Products HBeAg Calibrator	3 levels/3 sets liquid
117	1524693	VITROS Immunodiagnostic Products Anti-HBs Calibrators	3 vials (1 per level)
118	6802132	VITROS Immunodiagnostic Products HBsAg ES Calibrator	1 vial
119	1940667	VITROS Immunodiagnostic Products Anti-HCV Calibrator	1 level/ 1 set
120	1700863	VITROS Immunodiagnostic Products Anti-HIV 1 + 2 Calibrator	1 vial
121	6842780	VITROS Immunodiagnostic Products HIV Combo Calibrator	1 vial

Sr. No.	Product Code	Product Description	Pack Size
122	6844424	VITROS Immunodiagnostic Products C-peptide Calibrators	9 vials (3 per level)
123	6844453	VITROS Immunodiagnostic Products NT-proBNP II Calibrators	3 vials (1 per level)
124	6900448	VITROS Immunodiagnostic Products Anti-HTLV I/II Calibrator	1 vial (1 per level)
125	6199972	VITROS Immunodiagnostic Products VITROS IL-6 Calibrator	2 levels/ 3 sets
Controls			
Sr. No.	Product Code	Product Description	Pack Size
126	6199924	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls	1 Box-3x2 X 2 ml
127	6199921	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Controls	1 Box-3x2 X2 ml
128	6905560	VITROS Immunodiagnostic Products B•R•A•H•M•S PCT Controls	3 levels / 1 ml vials
129	6900040	VITROS Immunodiagnostic Products hs Troponin I Low Control	3 vials
130	1619360	VITROS Immunodiagnostic Products Anemia Controls	3 Sets/ Pack
131	1420025	VITROS Immunodiagnostic Products Metabolism Controls	3 Sets/ Pack
132	1315654	VITROS Immunodiagnostic Products Free Thyroid Controls	3 Sets/ Pack
133	6800835	VITROS Immunodiagnostic Products Anti-HAV IgM Controls	3 Sets/ Pack
134	6801463	VITROS Immunodiagnostic Products Anti-HAV Total Controls	3 Sets/ Pack
135	6802895	VITROS Immunodiagnostic Products Intact PTH Controls	3 Sets/ Pack
136	6800336	VITROS Immunodiagnostic Products NTx Controls	3 Sets/ Pack
137	1009406	VITROS Immunodiagnostic Products RE Controls	3 Sets/ Pack
138	6800660	VITROS Immunodiagnostic Products Testosterone Controls	3 Sets/ Pack
139	6842805	VITROS Immunodiagnostic Products Syphilis TPA Controls	3 sets of 2 vials/ Pack
140	1410646	VITROS Immunodiagnostic Products Total Thyroid Controls	3 Sets/ Pack
141	6844413	VITROS Immunodiagnostic Products NephroCheck Test Controls	3 sets of freeze-dried Controls 1, 2, and 3

Sr. No.	Product Code	Product Description	Pack Size
142	6800836	VITROS Immunodiagnostic Products Anti-HBc Controls	3 Sets/ Pack
143	6800834	VITROS Immunodiagnostic Products Anti-HBc IgM Controls	3 Sets/ Pack
144	6800837	VITROS Immunodiagnostic Products Anti HBe Controls	3 Sets/ Pack
145	6800389	VITROS Immunodiagnostic Products Anti-HBs Controls	3 Sets/ Pack
146	6800598	VITROS Immunodiagnostic Products HBsAg Controls	2 levels/ 3 sets
147	6800731	VITROS Immunodiagnostic Products Anti-HCV Controls	2 levels/ 3 sets
148	6800586	VITROS Immunodiagnostic Products Anti-HIV 1 + 2 Controls	3 levels/ 3 sets
149	6844507	VITROS Immunodiagnostic Products NT-proBNP II Control	3 vials
150	6842905	VITROS Immunodiagnostic Products Syphilis TPA Control	2 levels
151*	91474	Liquid QC Cardiac Marker Control VS	2 X 3 X 3 ml
152*	10820	Tumor marker control	Control level 1 - 3 X 3 ml Control level 2 - 3 X 3 ml (Control Level 3 X 3 ml)
153	6900449	VITROS Immunodiagnostic Products Anti-HTLV I/II Controls	3 sets of each control
154	6199973	VITROS IL-6 Controls	2 levels/ 3 set

Consumables			
155	1072693	VITROS Immunodiagnostic Products Signal Reagent	2 x 200 T
156	8389793	VITROS Immunodiagnostic Products Universal Wash Reagent	2 x 5 L
157	1831312	VITROS Immunodiagnostic Products Maintenance Pack	2 Packs
158	8430373	VITROS Immunodiagnostic Products High Sample Diluent A Reagent Pack	100 wells
159	8321200	VITROS Immunodiagnostic Products High Sample Diluent B Reagent Pack	100 wells
160	8642712	VITROS Immunodiagnostic Products High Sample Diluent A	4 bottles x 27ml
161	1435866	VITROS Immunodiagnostic Products High Sample Diluent B	4 bottles x 27ml
162	1877158	VITROS Immunodiagnostic Products System Cleaning Solution	2 x 1 litre bottles

Note: * Manufactured by Ortho Clinical Diagnostic's contract manufacturer.

Authorized Signatory

**Ana Parra
(APARRA)**

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Ana Parra
Sr. Associate, International Regulatory Affairs