| evaluate | assess | certify | assessors of quality

Certificate No. ICM-PC/91/R/2295-1

This is to certify that

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

Corporate Office : Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa – 403 202, India

(Refer Annexure I to Certificate for the list of certified workplaces)

has been found to conform to the requirements of

Indian Certification for Medical Devices Certification Scheme ICMED 13485 Plus (Ver.3)

This Certificate is valid for the following scope:

In Vitro Diagnostic Devices intended for Clinical Chemistry and Hematology

(a list of certified devices is contained in Annexure II, which forms an inseparable part of this Certificate)

Verification to Standard(s) : The list of applicable Standards is contained in Annexure III, which forms an inseparable part of this Certificate.

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Authorised Signatory

The authenticity of this document may be re-affirmed by writing to certification@zenith-worldwide.com. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law

Accreditation Body: National Accreditation Board for Certification Bodies (NABCB)
Quality Council of India (QCI), 2nd Floor, Institution of Engineers Building, Bahadur Shah Zafar Marg, New Delhi – 110 002, India
www.nabcb.qci.org.in

Issuing Authority: Zenith Quality Assessors Pvt. Ltd.
Office No. 01A, B-Wing, Siddhesh OPTIMUS, S. No. 211, Viman Nagar, Pune – 411 014, Maharashtra, India
www.zenith-worldwide.com

C/NABCB/ICMED13485Plus-MS/03/020126

Annexure-I to Certificate No. **ICM-PC/91/R/2295-1**

Issued to the Company

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

Workplaces and Scope of Activities :

Corporate Office : Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa – 403 202, India
Scope of Activities : Management, Human Resource, Regulatory Affairs, Purchase, Marketing & Sales

Site 1 : Plot Nos. S-124, S-125, Phase IIIB, Verna Industrial Estate, Verna, Goa - 403 722, India
Scope of Activities : Purchase

Site 2 : Plot No. L-130, Phase IIIB, Verna Industrial Estate, Verna, Goa – 403 722, India
Scope of Activities : Finished Goods Stores & Dispatch

Site 3 : Bldg. E, Plot No. M-46/47, Phase IIIB, Verna Industrial Estate, Verna, Goa - 403 722, India
Scope of Activities : Human Resource, Design & Development, Production, Quality Control, Quality Assurance, Stores & Dispatch

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Zenith Quality Assessors Pvt. Ltd. INDIA
Authorised Signatory

Annexure-II to Certificate No. **ICM-PC/91/R/2295-1**

Issued to the Company

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

I. In Vitro Diagnostic Devices intended for Clinical Chemistry

Sr. No.	Product Name	Brand Name	Catalogue Nos.
1	Albumin Kit	NIL	1101021150, 1101022150 1101023150, 1101021000
2	Auto Bilirubin Kit	NIL	1101040275, 1101042150
3	Bilirubin Kit	NIL	1101050035, 1101050075 1101052250, 1101052000
4	Calcium (ArsenazoIII) Kit	NIL	1103020075, 1103020025 1103022150, 1103020275 1103020375, 1103021000
5	Calcium (OCPC) Kit	NIL	1103010235, 1103010275 1103012150
6	Chloride Kit	NIL	1103030075, 1103030375
7	Cholesterol Kit	NIL	1102040075, 1102040275 1102042150, 1102042250
8	CK-MB Kit	NIL	1102070210, 1102070225 1102070275, 1102071000 1102070900
9	CK (NAC act) Kit	NIL	1102060210, 1102060225 1102060275, 1102061000 1102060900
10	Creatinine (EP) Kit	NIL	1101060015, 1101060035 1101060070
11	Creatinine (Kin) Kit	NIL	1101070220, 1101070235 1101070275, 1101072150 1101072500, 1101072250
12	Elyte 2 kit	ELYTE 2 KIT	1103050015
13	Elyte 3 Kit	ELYTE 3 KIT	1103060015
14	γ Glutamyl Transferase Kit	NIL	1102100102
15	Glucose Kit	NIL	1102110075, 1102112150 1102113150, 1102111000
16	Glycosylated Hemoglobin Kit	NIL	1101100010, 1101100025
17	HDL Cholesterol Kit	NIL	1102140075
18	Hemospot Kit	HEMOSPOT	1108020050 1108020100
19	Iron & TIBC Kit	NIL	1103070035, 1103070150

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Zenith Quality Assessors Pvt. Ltd. INDIA

Authorised Signatory

Annexure-II to Certificate No. **ICM-PC/91/R/2295-1**

Issued to the Company

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

In Vitro Diagnostic Devices intended for Clinical Chemistry (Contd.)

Sr. No.	Product Name	Brand Name	Catalogue Nos.
20	Lipase Kit (Turbidimetric Method)	NIL	1102180025, 1102180010 1102180075, 1102180500 1102181000
21	Magnesium kit	NIL	1103090025
22	Micro Protein Kit	NIL	1101150025, 1101150275
23	Phosphorus (UV) Kit	NIL	1101160075, 1101160275
24	SGOT Kit (Mod IFCC method)	NIL	1102200025, 1102200010 1102200075, 1102202150 1102201000, 1102205000
25	SGPT Kit (Mod IFCC method)	NIL	1102210025, 1102210010 1102210075, 1102212150 1102211000, 1102215000
26	Total Protein Kit	NIL	1101201150, 1101202150 1101203150, 1101201000
27	Triglycerides Kit	NIL	1102220025, 1102220075 1102220275, 1102222150
28	Urea (UV) Kit	NIL	1102250075, 1102250025 1102250275, 1102252150 1102251000, 1102255000
29	Urea (Berthelot) Kit	NIL	1102240075, 1102240375 1102242150, 1102240150 1102240275
30	Uric Acid Kit	NIL	1102260025, 1102260075 1102260275, 1102262150
31	Creatinine (Enzymatic) Kit	NIL	1102080040, 1102080240
32	Potassium Kit	NIL	1103100015, 1103100050
33	Sodium Kit	NIL	1103110015, 1103110050
34	HDL-D Cholesterol Kit	NIL	1102150040, 1102150160 1102150240, 1102150280 1102151000

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Zenith Quality Assessors Pvt. Ltd. INDIA
Authorised Signatory

Annexure-II to Certificate No. **ICM-PC/91/R/2295-1**

Issued to the Company

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

In Vitro Diagnostic Devices intended for Clinical Chemistry (Contd.)

Sr. No.	Product Name	Brand Name	Catalogue Nos.
35	LDL-D Cholesterol Kit	NIL	1102170040, 1102170160 1102170240, 1102171000
36	Acid Phosphatase Kit (α Naphthylphosphate Kinetic)	NIL	1102010102, 1102010302
37	Alkaline Phosphatase Kit (pNPP Kinetic Method)	NIL	1102020103, 1102020515 1102022015
38	α-Amylase Kit	NIL	1102030210, 1102030230
39	HDL Cholesterol Ppt. SET	NIL	1102130010, 1102130225
40	Hemocor C	HEMOCOR-C	1101125122
41	LDH (P-L) Kit	NIL	1102160025, 1102160275 1102161000, 1102165000
42	G-Six (Kin) Kit	G-SIX Kit	1102120005, 1102120055 1102123755, 1102121500
43	Zinc Kit	NIL	1103130025
44	Copper Kit	NIL	1103040025
45	Chloesterol SR Kit	NIL	1102050075, 1102050020 1102051000, 1102052150 1102054250
46	Triglycerides SR Kit	NIL	1102230075, 1102230020 1102232150, 1102234250 1102230550
47	Iron Kit	NIL	1103080035, 1103080150 1103081035, 1103081000 1103081075
48	Adazyme LS	ADAZYME LS	1102310010, 1102310025
49	Adazyme Control Level I	ADAZYME Control Level I	203060011
50	Adazyme Control Level II	ADAZYME Control Level II	203060021

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Zenith Quality Assessors Pvt. Ltd. INDIA

Authorised Signatory

Annexure-II to Certificate No. **ICM-PC/91/R/2295-1**

Issued to the Company

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

In Vitro Diagnostic Devices intended for Clinical Chemistry (Contd.)

Sr. No.	Product Name	Brand Name	Catalogue Nos.
51	γ-Glutamyl transferase Kit LS (Kin)	NIL	1102280025, 1102280075
52	Total Bilirubin Kit	NIL	1101050500, 1101050275 1101052150
53	Direct Bilirubin Kit	NIL	1101051502, 1101052502 1101050150
54	Bilirubin T&D Kit (DCA Method)	NIL	1101240275, 1101240240 1101242150, 1101242250 1101241002
55	Total Bilirubin Kit (DCA Method)	NIL	1101261250, 1101260040
56	Direct Bilirubin Kit (DCA Method)	NIL	1101251250, 1101250040
57	Alkaline Phosphatase kit AMP (IFCC Method)	NIL	1102270025, 1102270075 1102272150
58	Lipase Kit (Colorimetic Method)	NIL	1102300025, 1102300075 1102300010, 1102301000
59	BornSafe Biotinidase (Neonatal Biotinidase Deficiency Screening Assay)	BORNSAFE BIOTINIDASE	1122050096
60	BornSafe G6PD (Neonatal G6PD Deficiency Screening Assay)	BORNSAFE G6PD	1122020096
61	BornSafe MSUD (Neonatal Maple Syrup Urine Disease (MSUD) Deficiency Screening Assay)	BORNSAFE MSUD	1122030096
62	BornSafe PKU (Neonatal Phenylketouria Deficiency Screening Assay)	BORNSAFE PKU	1122010096
63	BornSafe T.GAL (Neonatal Total Galactose (T.GAL) Deficiency Screening Assay)	BORNSAFE T.GAL	1122040096
64	Blood Spots Collection Card for New Born Screening	Bornsafe NBS 903 Blood Spots Collection Card	1122060100, 1122060010

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Zenith Quality Assessors Pvt. Ltd. INDIA
Authorised Signatory

Annexure-II to Certificate No. **ICM-PC/91/R/2295-1**

Issued to the Company

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

II. In Vitro Diagnostic Devices Intended for Hematology

Sr. No.	Product Name	Brand Name	Catalogue Nos.
1	Hemocor Hb Standard	HEMOCOR	1101110010
2	Hemosafe SLS	HEMOSAFE SLS	1101141000
3	Diluent	DILUENT	1109020020, 1109020005 1109020001
4	Lyse	LYSE	1109031000, 1109030500 1109030250
5	Cleaner	CLEANER	1109011000, 1109010250 1109012050
6	Glycosylated Hemoglobin Control	NIL	1101230001
7	Concentrated Cleanser	CONCENTRATED CLEANSER	1109050250, 1109050075
8	Diluent Reagent	DILUENT REAGENT	1109060005, 1109080020 1109180020, 1109180005
9	Lyse Reagent	LYSE REAGENT	1109090500, 1109190500

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Zenith Quality Assessors Pvt. Ltd. INDIA
Authorised Signatory

Annexure-III to Certificate No. **ICM-PC/91/R/2295-1**

Issued to the Company

Coral Clinical Systems – A Division of Tulip Diagnostics (P) Ltd.

Verification to Standard(s) :
EN 13612:2002, ISO 23640:2011

Initial Certification : 17/02/2026
Valid until : 16/02/2029

Zenith Quality Assessors Pvt. Ltd. INDIA

Authorised Signatory