LabAnalysis
LIFE SCIENCE

GDUFA Self-ID Confirmation Statement – FY2025

LabAnalysis srl hereby confirms that the following facilities, sites and organizations have been electronically self-identified with the United States Food and Drug Administration for FY2025

12 June 2024

Signature
Date

Giuseppe Ceramelli
Qualified Person – Livorno site
LabAnalysis srl
Telephone number +39-0385287128
Fax:+39-038557311
e.mail: giuseppe.ceramelli@labanalysis.it

Facilities/Sites/Organizations Names and Addresses				Self-Identified Yes or No
Registrant - LabAnalysis Life Science srl (440209974)				Yes
Contact	**Address**	**Telephone Number**	**Email Address**	
Giuseppe Ceramelli	Address: Via Europa 5 City, State, Zip: Casanova, Lonati, 27041 Country: ITA	+39-0385-287128	giuseppe.ceramelli@labanalysis.it	
Facility				
Name	**Address**	**ID DUNS / FEI**	**Business Operations**	
LabAnalysis Life Science srl	Address: Via Domenico Cimarosa 105 City, State, Zip: Livorno, 57124 Country: ITA	440209974 / 3000979323	API/FDF analytical testing	
Contact	**Address**	**Telephone Number**	**Email Address**	
Giuseppe Ceramelli	Address: Via Europa 5 City, State, Zip: Casanova, Lonati, 27041 Country: ITA	+39-0385-287128 FAX: +39-0385-57311	giuseppe.ceramelli@labanalysis.it	

Revised: 05/2024

U.S. FOOD & DRUG ADMINISTRATION

1/11/2018

Food and Drug Administration
Office of Regulatory Affairs
Office of Pharmaceutical Quality Operations
Division of Foreign Pharmaceutical Quality Inspections
12420 Parklawn Dr. Rm 2038
Rockville, MD 20852, U.S.A.

Giuseppe Ceramelli, Life Science Manager
SGS Sertec S.R.L.
Via Domenico Cimarosa 95/105
Livorno, 57124 Italy

Reference: Inspection Date(s): 09/28/2017 - 09/29/2017

Location: SGS Sertec S.R.L.
Via Domenico Cimarosa 95/105
Livorno, 57124 Italy

Dear Mr. Ceramelli:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at 985-249-7936 x 1104.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

/S/ for Claire Minden

Claire Minden
Acting Branch Chief
Foreign Pharmaceutical Quality Inspections

FEI: 3000979323
Enclosure: Establishment Inspection Report (EIR)