



**FDA U.S. FOOD & DRUG**  
ADMINISTRATION

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.

1/11/2018

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](http://www.fda.gov).

Sincerely,

Claire Minden  
Acting Branch Chief  
Foreign Pharmaceutical Quality Inspections

FEI: 3000979323

Enclosure: Establishment Inspection Report (EIR)

U.S. Food and Drug Administration  
[www.fda.gov](http://www.fda.gov)



**GDUFA Self-ID Confirmation Statement – FY2021**

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 FY2021.

  
 \_\_\_\_\_  
 Signature  
 Giuseppe Ceramelli

May 11, 2020  
 \_\_\_\_\_  
 Date

Qualified Person  
 LabAnalysis srl – Livorno site  
 Telephone number +39-0385-287128  
 e.mail: giuseppe.ceramelli@labanalysis.it

Facilities/Sites/Organizations Names and Addresses				Self-Identified Yes or No
<b>Registrant - LabAnalysis srl (440209974)</b>				Yes
<b>Contact</b>  Giuseppe Ceramelli	<b>Address</b> Address: Via Domenico Cimarosa 95/105 City, State, Zip: Livorno, 57124 Country: ITA	<b>Telephone Number</b> +39-0385-287128	<b>Email Address</b> giuseppe.ceramelli@labanalysis.it	
<b>Facility</b>				
<b>Name</b> LabAnalysis srl	<b>Address</b> Address: Via Domenico Cimarosa 95/105 City, State, Zip: Livorno, 57124 Country: ITA	<b>ID/FEI</b> 440209974 / 3000979323	<b>Business Operations</b> analysis	
<b>Contact</b>  Giuseppe Ceramelli	<b>Address</b> Address: Via Europa 5 City, State, Zip: Casanova, Lonati, 27041 Country: ITA	<b>Telephone Number</b> +39-0385-287128	<b>Email Address</b> giuseppe.ceramelli@labanalysis.com	
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Revised: 5/2020