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**OGGETTO: Dichiarazione di unicità per la piattaforma di Live Cell Imaging
IncuCyte SX5**

DICHIARAZIONE

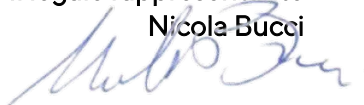
Ai sensi degli artt.46 e 47 del D.P.R. 445/2000 e successive modifiche ed integrazioni

Il sottoscritto Nicola Bucci, nato a Bollate (MI) il 24.06.1966 e residente a Cesate (MI) Via Puccini 109, in qualità di legale rappresentante della Sartorius Italy S.r.l., con sede legale ed amministrativa in Grassano Bagno a Ripoli (FI) Via A. Meucci, 4 C.F./P.I. 05748910485, tel 055/634041 fax 055/6340526 e-mail: mecsales.italy@sartorius.com

DICHIARA

che Sartorius è la sola azienda che produce e distribuisce direttamente la piattaforma di Live Cell Imaging IncuCyte SX5 che presenta ad oggi, a nostra conoscenza, caratteristiche uniche sul mercato. Tali caratteristiche sono descritte dettagliatamente nel documento "Sole Source IncuCyte SX5" che alleghiamo alla presente dichiarazione.

Il legale rappresentante
Nicola Bucci



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Reference: Sole Source Document: Incucyte SX5

Incucyte® SX5 Live-Cell Analysis System

The Incucyte® SX5 Live-Cell Analysis System is the only Live Cell Imaging System on the market with the following capabilities:

1. The Incucyte® SX5 automated image acquisition and analysis system operates and captures images from within a standard tissue culture incubator so that precise control of temperature, humidity and other environmental factors such as CO₂ and O₂ can be maintained. This provides:
 - a. **Uninterrupted incubation** – up to six microplates can be imaged simultaneously without being removed from an incubated environment. Other instruments require cells to be subjected to room temp and environment in order to image multiple vessels in parallel.
 - b. **Auditable and consistent gas/temperature concentrations** – tissue culture incubators are designed solely for the purpose of maintaining cells in a consistent gas/temperature/humidity environment and are a trusted instrument in the cell culture laboratory. The volume of environment being maintained is large in contrast to onboard incubator environments provided by most instruments. Small volumes are difficult to maintain at a consistent, precise gas/temperature/humidity level. In addition, standard tissue culture incubators will record temperature/gas/humidity readings, providing an audit trail. This is generally not offered with imaging systems and instrument-specific incubators.
 - c. **Attractive footprint** – since the Incucyte® SX5 sits inside a standard piece of equipment already present in the lab, additional bench space is not needed.
2. Incucyte® SX5 optics are mobile, meaning that the **optics move to the areas being imaged**. The cell culture vessels remain stationary during this process. Stationary optics and stage driven vessel movement are not acceptable when imaging sensitive or non-adherent cell types.
3. **Incucyte® SX5 optics do not need to be adjusted**. The objectives do not need to be adjusted for any reason. Some instruments have optics with correction collars that need to be adjusted, and may be difficult to access.
4. The Incucyte® SX5 **is capable of imaging in parallel any mixture of 6 assay plates** that conform to the ANSI/SLAS standard for assay plates.

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Rainer Lehmann

These include 384-well microplates, 96-well microplates, 48-well plates, 24-well plates, 12-well plates, and 6-well plates.

5. The Incucyte® SX5 accommodates the following but is not limited to the following plastic tissue culture vessels: 92.6 cm² Roboflask, 500 cm² Tripleflask, 84 cm² Autoflask, 225 cm² flasks, 185 cm² flasks, 182 cm² flasks, 175 cm² flasks, 162 cm² flasks, 150 cm² flasks, 75 cm² flasks, 25 cm² flasks, 35mm dishes, 60 mm dishes, 100mm dishes, 150mm dishes, chambered slides and microslides.
6. The Incucyte® SX5 provides fully **automated, hands-free operation** for periods exceeding 25 days and is designed to utilize auto-focus and auto-exposure without intervention during this time period. The Incucyte® SX5 returns to the same location in a repeated fashion without error over this same time period.
7. The Incucyte® SX5 software accommodates the entire user workflow with a single, networked software package that leverages a simple to use, guided user interface. New users can generally begin setting up experiments on their own and then perform visual inspection and generate graphs that are ready for publication after one training session. It is possible to learn the software without training by utilizing the provided user manual.
 - a. The Incucyte® SX5 base software package has all the tools necessary to perform automated acquisition and subsequent viewing and analysis for 2D cultures. Purpose-built add-ons are available to easily address specific applications such as cell-by-cell analysis, 3D spheroid cultures, chemotaxis, scratch wound migration, neurite outgrowth, and angiogenesis. Having application specific workflows is a unique approach compared to “tool box” approaches that require users to determine which tools to use and when.
 - b. The Incucyte® SX5 software is capable of generating label free, time based, growth curves for cells in 2D and 3D (e.g. spheroid) cultures.
 - c. The Incucyte® SX5 software is able to mask, quantify and generate time based curves based on fluorescence **metrics from thousands of images using an intuitive interface** including but not limited to: Fluorescent Count, Fluorescent Average Area, Fluorescent Total Area, Fluorescent Confluence, Fluorescent Mean Intensity, Fluorescent Average Integrated Intensity, Fluorescent Total Integrated Intensity, and Fluorescent Eccentricity.
 - d. Control of the Incucyte® SX5 system via software is distributed over a network and the client software can elicit control of the automated image acquisition and analysis system from any networked computer. Unlimited licensees of the client software are available. The client software does not operate using a client computer license key or dongle. This provides seamless yet secure access to the software for all users.

- e. The Incucyte® SX5 performs whole-well imaging for selected vessels and include software for image navigation and panning.
- 8. The Incucyte® SX5 has a fluorescence calibration system that **allows for comparison of fluorescence-based metrics derived from images on one instrument to metrics derived from images on another instrument**. The calibration system also enables comparison of intensity values for images that are captured with different objectives and at different acquisition times. Last, calibration enables automated correction of camera offset, illumination shape, and background signal from sources such as light leakage and auto-fluorescence of optical elements (e.g., dark-field and flat-field corrections).
- 9. The Incucyte® SX5 has three interchangeable Optical Modules which include high definition phase contrast optics, multiple fluorescence excitation/emission channels, and the illumination source for these channels. Green/Orange/Near IR (included with the Incucyte® SX5; Green: ex453-485nm, em494-533nm; Orange: ex546-568nm, em576-639nm; NIR: ex648-674nm, em685-756nm), Green/Red (optional; Green: ex441-481nm, em503-544nm; Red: ex567-607nm, em622-704nm), and Metabolism (optional; Dual Ex/Single Em: ex473-498nm, ex524-550nm, em565-591nm or Orange: ex524-550nm, em565-591nm; and NIR: ex648-674nm, em685-756nm).
- 10. The Incucyte® SX5 has high definition optics that enable imaging of standard 96- and 384-well tissue culture plates without any sidewall or meniscus effects.
- 11. The Incucyte® SX5 has the following objectives on an automated turret: 4x PLAN, 10x PLAN FLUOR, and 20x PLAN FLUOR.
- 12. The Incucyte® SX5 uses a CMOS detector with low read noise and a linear response to changes in fluorescence.
- 13. The Incucyte® SX5 has data storage capacity of **at least 27 terabytes (TB) in the form of a RAID Array and is expandable to 60 TB with an additional storage module**.

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