CLAIMS

[Claim 1]. An automated apparatus suitable for the preparation of genetically transformed cells from biological fluids comprising:

(i) an operating unit (80) that is rotatable around its center about a horizontal axis (19),

(ii) a central axis shaft (16) holding the operating unit (80) providing support and electrical power,

characterized in that the operating unit (80) comprises a rotating concentric hollow processing chamber (1) having

- a top part that is a half sphere with the round part facing up with a protruding hole (3) at its very top;
- bottom edges (7) of the half sphere positioned between a quarter and halfway of the total height of the rotating concentric processing chamber (1) forming a perpendicular angle with the bottom part of the concentric hollow processing chamber (1) which narrows down into a funnel shape (6) that follows a concave arched curve with a bottom hole (4) at its very bottom;

and wherein said operating unit (80) is configured to shift said rotating concentric hollow processing chamber (1) from a vertical (14) to a horizontal position (15) conferring different operations to said automated apparatus.

[Claim 2]. The automated apparatus of claim 1, wherein the rotating concentric processing chamber (1) further comprises one or more side hole (5) circularly arranged above the bottom hole (4).

[Claim 3]. The automated apparatus according to any of claims 1-2, wherein the rotating concentric hollow processing chamber (1), is fitted with an inlet stator (8) at its top and an outlet stator (10) at its bottom allowing liquids to be pumped in and out of the rotating concentric hollow processing chamber (1).

[Claim 4]. The automated apparatus according to any of claims 2-3, wherein an actionable plug (13) shaped to fit the bottom hole (4) of the rotating concentric hollow processing chamber (1) can be engaged (32) or disengaged (34) to respectively block or unblock the one or more circularly arranged side hole (5).

[Claim 5]. The automated apparatus according to any of claims 1-4, wherein the rotating concentric hollow processing chamber (1) is connected at both its bottom (10) and top stators (8) to two independent sets composed of a disposable peristaltic pump head (58, 60) connected to a disposable multiple-way rotary selector valve head (57, 61) connected to several reagent or product pouches so as to form a disposable kit (66).

[Claim 6]. The automated apparatus according to any of claims 1-5, wherein the operating unit (80) is shaped as an hexagonal prism (96) that possesses different functions for each of the six operating unit faces (87, 88, 89, 91, 92, 95) and that can accommodate the rotating concentric hollow processing chamber (1) in a rotor housing (95) on one of the faces.

[Claim 7]. The automated apparatus according to claim 6, wherein the six operating unit faces (87, 88, 89, 91, 92, 95) comprise:

two faces that are chambers engineered for the storage of liquid bags that can be temperature controlled (87, 89);

one face which is a rotor housing chamber (95) that holds the rotating concentric hollow processing chamber (1) and is equipped with an actionable magnetic array (70);

one face (91) that comprises a user interface (86) as well as attachment points for a peristaltic pump head (58) and multiple-way rotary selector valve head (57);

one face (92) that comprises attachment points for a peristaltic pump head (60) and multiple-way rotary selector valve head (61) and,

one face (88) that contains data input/output connectors, power connectors as well as venting for temperature control.

[Claim 8]. The automated apparatus according to claim 7, wherein the actionable magnetic array (70) consists in an arched shape designed to fit the edge (7) of the rotating concentric hollow processing chamber (1) when engaged and further comprising one or more high magnetic field strength magnets (73).

[Claim 9]. A process for the processing of biological fluids including biological solid separation, aggregate resuspension, reagents and/or cells incubation, magnetic separation of cells of interest and cell culture expansion in a rotating concentric hollow processing chamber (1) that can receive fluids and can be operated in multiple orientations in space by means of an operating unit (80) equipped with a set of reagents and bags part of a disposable kit (66) and capable of performing:

- when oriented vertically (14) centrifugation in order to separate liquids from solids and volume adjustment;
- when oriented horizontally (15) solid resuspension, magnetic beads magnetic attachment, solution incubation and mixing and volume adjustment;

characterized in that, the set of operations to perform said processing of biological fluids comprises a chained combination and/or repetition of procedures of volume adjustment and centrifugation when the rotating concentric hollow processing chamber (1) is vertical (14) and,

low speed rotation, fast sequential clockwise and counterclockwise rotations, magnetic beads magnetic attachment, solution incubation and mixing when the rotating concentric hollow processing chamber (1) is horizontal (15).

[Claim 10]. The process for the processing of biological fluids according to claim 9, wherein the operation for biological solid separation is performed by:

- positioning the rotating concentric hollow processing chamber (1) vertically (14) by a rotation of the operating unit (80) and filling it with a biological suspension (100) that is then centrifuged by spinning the rotating concentric hollow processing chamber (1) along its axis (14) for a set time at a set speed to generate a centrifugal force, which

results in the biological solids separating from the liquid and aggregating (102) on the edge (7) of the rotating concentric hollow processing chamber (1);

- followed by stopping progressively the rotation of the rotating concentric hollow processing chamber (1), resulting in the liquid phase (101) flowing down and the solid phase (102) remaining attached to the edge (7) of the rotating concentric hollow processing chamber (1);

- the resulting liquid phase (101) being pumped out at the outlet stator (10).

[Claim 11]. The process for the processing of biological fluids according to claim 9, wherein the operation for aggregate resuspension is performed by:

positioning the rotating concentric hollow processing chamber (1) horizontally (15) by a rotation of the operating unit (80), and

rotating the rotating concentric hollow processing chamber (1) about its horizontal axis (15) by series of fast sequential clockwise and counterclockwise rotations for a set time, and

detaching ~~the~~ an obtained aggregated solid (102) and suspending it in ~~the~~ a liquid phase (106).

[Claim 12]. The process for the processing of biological fluids according to claim 9, wherein the operation for reagents and/or cells incubation, is performed by:

positioning the rotating concentric hollow processing chamber (1) horizontally (15) by a rotation of the operating unit (80), mixing ~~the~~ a biological suspension (~~106~~100) in the processing chamber (1) with a reagent of interest and rotating the concentric processing chamber (1) about its central axis by a low speed rotation for a set time at a set temperature.

[Claim 13]. The process for the processing of biological fluids according to claim 9, wherein the operation for magnetic separation of cells of interest, is performed by:

- incubating a biological suspension (103) with binding magnetic selection beads (104); orienting the rotating concentric hollow processing chamber (1) to a horizontal position (15) by a rotation of the operating unit (80); bringing the magnetic array (70) close to the edge (7) of the rotating concentric hollow processing chamber (1), resulting in the attraction of the magnetic beads (104);

- rotating the operating unit (80) to position the rotating concentric hollow processing chamber (1) vertically (14) with the magnetic array (70) kept in close contact with the edge (7) of the rotating concentric hollow processing chamber (1), which results in the unwanted suspension (103) to flow to the bottom of the rotating concentric hollow processing chamber (1) and then be pumped out to a waste bag (62) while the cells of interest, attached to the magnetic beads (104) are magnetically resting at the edge (7); and retracting the magnetic array (70) to allow the magnetic beads (104) to freely flow.

[Claim 14]. The process for the processing of biological fluids according to claim 9, wherein the operation for cell culture expansion, is performed by:

having an homogeneous cell suspension (106) residing in cell culture medium inside the rotating concentric hollow processing chamber (1) oriented horizontally (15) by the action of the operating unit (80) performing low speed rotation so as to perform an incubation operation for a sufficient time;

after said sufficient time, the rotating concentric hollow processing chamber (1) is oriented vertically (14) by the action of the operating unit (80) and sampling is performed via a sampling port (64) in order to assess the cell culture (106) state, the sampling port (64) is connected to an outlet multiple-way rotatable selector valve head (61) connected to the outlet stator (10) of the rotating concentric hollow processing chamber (1); which in the case of a need for medium renewal a biological solid separation operation is performed with the old culture medium (101) being evacuated from the rotating concentric hollow processing chamber (1) and new cell culture medium is added (105),

the procedure is followed by an aggregate resuspension followed by further incubation until cell count is satisfactory.