CLAIMS

1. Releasing stopper (1), suitable for and/or intended to be removably coupled with a container (30) and configured to contain and selectively release a substance (S) in the container (30), the stopper (1) comprising:

- a first body (1a) configured to be directly coupled with the container (30) and comprising a coupling element (10) suitable for allowing the removable fastening of the stopper (1) in correspondence of an opening of the container (30) defining a first mounting configuration of the stopper on the container wherein, preferably, the stopper closes the container;

- a second body (1b), coupled and movable with respect to the first body (1a) and defining with the first body (1a) at least one reservoir (20) configured to contain the substance (S), the reservoir (20) being insulated from the outer environment in at least a first closed configuration of the stopper,

- a closing element (15), constituting at least a portion of the reservoir wall (20) and facing the inside of the container (30) in the mounting configuration, the closing element (15) being configured to be selectively openable and/or breakable, defining at least a second open configuration of the stopper, through the action of a perforation or opening element (40, 41, 42) different from the stopper (1), different from the container (30) and removably housed within the container (30), to make the reservoir (20) be in communication with the inside of the container (30);

wherein the second body (1b) comprises a cavity (6) configured to allow the removable engagement of an ending portion of the perforation or opening element (40, 41, 42); the stopper being configured to allow the introduction by contrast only when in open configuration.

2. Stopper according to claim 1, wherein the second body (1b) is axially and translatably movable with respect to the first body along a predefined axis (X) of the stopper (1) and/or wherein at least a lower portion of the second body (1b) is movably housed inside the first body (1a), to define the reservoir (20) and/or

wherein the reservoir (20) is confined between the first body (1a), in particular at least by a lateral wall of the first body (1a), and the second body (1b), in particular a lower portion (28) of the second body (1b), more in particular being centrally limited by the lower portion (28) of the first body.

3. Stopper according to claim 2, comprising a tapered portion or element (14), optionally positioned on the first body (1a) suitable for facilitating the targeting and/or driving of at least part of the perforation element (40, 41, 42) towards the closing element (15), wherein the tapered portion (14) is positioned in a position which is longitudinally outer with respect to the closing element (15) and/or faces toward the closing element (15) and/or wherein the tapered portion or element (14) is integral to the first body (1a) and is substantially funnel-shaped, and is configured to be accessible from the inside of the container (30) and/or wherein the closing element (15) is configured to be selectively openable and/or breakable, defining at least the second open configuration of the stopper, through the action of a perforation or opening element (40, 41, 42) different from the stopper (1) and different from the container (30).

4. Stopper according to one or more of the previous claims,

wherein the second body (1b) comprises a cavity (6) configured to allow the removable engagement of an ending portion of the perforation or opening element (40, 41, 42) through introduction by contrast; the stopper being configured to allow the introduction by contrast only when in open configuration in substantial proximity or correspondence of the configuration of minimum axial extension.

5. Stopper according to one or more of the previous claims, suitable for and/or intended to be removably coupled against a head portion of the container (30), and/or wherein the first body (1a) is configured and intended to be removably coupled against a head portion of the container (30), in particular wherein the first body (1a) is configured for being rigidly united and/or fixed on a

head portion of the container (30) and/or is configured for striking against a head portion of the container (30).

6. Stopper according to one or more of the previous claims, wherein:

- the closing element (15) is positioned on the first body (1a) and/or is integral to the first body (1a) and/or, at least when the stopper is in the first closed configuration, the closing element is integral to the first body (1a);

- and/or wherein the closing element (15) is a waterproof element, configured and specifically designed to retain solids, in particular powders, liquids and/or gases.

7. Stopper according to one or more of the previous claims, wherein:

- the closing element is a membrane (15) or collapsible septum, optionally provided with a weakening portion; and/or wherein

- the closing element is configured to withstand the pressure induced on the reservoir (20) by an axial compression of the second body (1b) with respect to the first body (1a), optionally manually induced by an operator; the closing element comprising a weakening portion suitable to break first by mechanical contrast induced by the perforation or opening element (40, 41, 42); and/or wherein

- in the open configuration the substance is at least partially released into the container (30) and/or wherein the stopper is configured to release the substance into the container (30) when in the open configuration, in particular by keeping, when coupled to the container (30), an insulation of the volume overall identified by the container (30) - reservoir (20) assembly insulated from the outer environment and/or in particular by causing an exclusive release of the substance through the opening identified by the breaking of the closing element (15).

8. Stopper according to one or more of the previous claims, comprising a retaining element of the closing element, configured to prevent the release and/or fall of the closing element (15) within the container (30); the retaining element

being in particular configured to retain the closing element (15) inside the first body (1a);

the retaining element comprising a shoulder (15s) against which the closing element (15) rests or folds when in contrast with the perforation or opening element (40, 41, 42);

the shoulder (15s) being positioned in substantial correspondence of a channel between the reservoir (20) and the closing element.

9. Stopper according to claim 8,

- wherein in the open operating configuration, the closing element (15) is retained by the shoulder (15s) and is trapped between the channel and part of the perforation or opening element (40, 41,42) positioned within the channel,

- and wherein the closing element (15) is configured to break without releasing splinters or portions.

10. Stopper according to one or more of the previous claims, wherein:

- the second body (1b) is movable with respect to the first body (1a) and defines through its axial movement at least a configuration of maximum axial extension of the stopper (1) along a longitudinal axis (X) and a configuration of minimum axial extension of the stopper (1) along the longitudinal axis (X);

- the first closed configuration comprises the maximum axial extension configuration and the second open configuration comprises the minimum axial extension configuration;

- the second open configuration takes place in correspondence of a longitudinal extension, optionally substantially intermediate, between the longitudinal extension corresponding to the configuration of maximum extension and the longitudinal extension corresponding to the configuration of minimum longitudinal extension.

11. Stopper according to one or more of the previous claims,

- wherein the first body (1a) comprises an upper cavity (1c), laterally delimited by a lateral wall, and a lower cavity separated each other by the presence of the closing element (15),

- and wherein the second body (1b) is configured to be installed in correspondence of the upper cavity (1c) of the first body (1a).

12. Stopper according to one or more of the previous claims, wherein:

- the second body (1b) comprises an intermediate section comprising a sealing and linear translation limitation element (2), configured to determine a confinement of the reservoir (20) volume and to limit the stroke of the second body (1b) with respect to the first body (1a) between the configuration of maximum linear extension and the configuration of minimum linear extension of the stopper,

- wherein the second body (1b) comprises an upper portion (25) and a lower portion (28) with respect to which the intermediate section is longitudinally interposed,

- wherein the diameter substantially identified by the radially outermost section of the sealing element (2) is significantly greater than the diameter identified by the upper portion (25) and/or the lower portion (28) of the second body (1b),

- wherein the sealing element (2) comprises, optionally at a first upper height, a shoulder (2s) configured to engage in use with a retention portion (23) prominent from the inner face of the lateral wall of the first body (1a), the engagement between the retention portion (23) and the shoulder (2s) being such as to determine the impossibility of complete extraction of the second body (1b) from the first body (1a) when the latter has been previously inserted,

- and/or wherein the sealing element (2) comprises a delimiting wall (2g) specifically configured to determine the sealing and confinement of the reservoir volume (20), the delimiting wall having a conformation such as to also determine the limitation of the translation of the second body (1b) with respect to the first body (1a) in the configuration of minimum axial extension.

13. Stopper according to one or more of the previous claims, wherein the first body (1a) comprises an annular recess, optionally positioned at a substantially intermediate height between a minimum and a maximum height defined by the first body (1a) and/or positioned at a height substantially corresponding to the height at which the closing element (15) is located; the annular recess being configured to speed up the cooling of the first body (1a), in particular of the portion of the first body (1a) in correspondence of which it is positioned with respect to ending portions of the first body (1a).

14. Stopper according to one or more of the previous claims when depending on claim 10, wherein:

- the first body (1a) comprises a pressure release element (29), configured to allow the evacuation of a predefined volume of air when the second body (1b) is introduced into the first body (1a),

- and wherein the pressure release element (29) is configured to allow the evacuation of a predefined volume of air when the second body (1b) is introduced into the first body (1a) in a non-operational mounting configuration of the second body (1b) into the first body (1a), without affecting the tightness of the reservoir (20) itself when at least the maximum axial extension configuration is reached,

optionally wherein the pressure release element (29) comprises a notch positioned in correspondence of a head portion of the inner face of the lateral wall of the first body (1a) and/or positioned in correspondence of a head portion of the upper cavity (1c).

15. Stopper according to one or more of the previous claims,

- wherein the second body (1b) has a recess (5), optionally bell-shaped, configured to be coupled with a bottom portion of the reservoir (20) and having a shape substantially following the shape identified by the bottom of the reservoir (20),

- optionally wherein the recess (5) opens on the cavity (6), the cavity (6) having a plurality of ribs (7) of retention of the perforation or opening element (40, 41, 42).

16. Container (30) for the storage of a biological sample, the container comprising a body openable at least in correspondence of at least one own first portion (33) and provided with a lateral wall and a bottom wall (32) coupled to the lateral wall, the container (30) being configured to house within it a microbiological sample collection device provided with a swab (42) and a rod and to be movably coupled with a stopper (1) in accordance with one or more of claims 1-15, such as to realize the perforation or opening element (40, 41, 42);

the container (30) having a longitudinal development and a shape of its bottom wall (32) such that and configured in such a way that an ending portion (41) of the rod of the microbiological sample collection device opposite to the portion in correspondence of which the swab is located (42) after the removable coupling of the stopper (1) to the container (30) determine a perforation of the closing element (15) and a partial introduction of the ending portion (41) of the rod (40) within the first body (1a).

17. Container according to claim 16, comprising a substantially "V"-shaped bottom portion (32), optionally connected without interruption with the lateral wall of the container (30), wherein in correspondence of the bottom portion (32) the lateral wall progressively tapers towards the centre of the container body (30); the bottom portion (32) being configured to exert a centering of the rod (40) and/or of the swab (42) for collecting the biological samples along the longitudinal axis (X) of the container (30),

the bottom portion (32) cooperating with the guide portion (13s, 13v) of said stopper (1), and in particular with the second wall (13s), in order to contribute to the centring of the rod (40) along said longitudinal axis (X).

18. Kit comprising:

- a container (30), configured to be closed through a releasing stopper (1), optionally a container according to claim 16 or claim 17,

- an element (40, 41, 42) for the collection and storage of a biological sample, suitable for realizing a perforation or opening element for the releasing stopper (1),

- the releasing stopper (1), suitable for being removably coupled with the container (30) and configured to contain and release a substance (S) in the container (30), the releasing stopper (1), being a stopper suitable and/or intended to be removably fastened to a container (30) and configured to contain and selectively release a substance (S) in the container (30), the stopper (1) comprising:

- a first body (1a) configured to be directly coupled with the container (30) and comprising a coupling element (10) suitable for allowing the removable fastening of the stopper (1) in correspondence of an opening of the container (30) defining a first mounting configuration of the stopper on the container wherein, preferably, the stopper closes the container;

- a second body (1b), coupled and movable with respect to the first body (1a), preferably axially and translatably movable along a predefined axis (X) of the stopper (1), and defining with the first body (1a) at least a reservoir (20) configured to contain the substance (S), the reservoir (20) being insulated from the outer environment in at least a first closed configuration of the stopper,

- a closing element (15), constituting at least a portion of the reservoir wall (20) and facing inward the container (30) in the mounting configuration, the closing element (15) being configured to be selectively openable and/or breakable, defining at least a second open configuration of the stopper, through the action of a perforation or opening element (40, 41, 42) different from the stopper (1), different from the container (30) and removably housed inside the container (30), to put the reservoir (20) in communication with the inside of the container (30);

wherein the second body (1b) comprises a cavity (6) configured to allow the removable engagement of an ending portion of the perforation or opening

element (40, 41, 42); the stopper being configured to allow the introduction by contrast only when in open configuration.

19. Method for the distribution of substances within a releasing stopper according to one or more of the preceding claims 1-15, or a kit according to claim 18, the method comprising the following steps:

- a step of positioning the substance within the first body (1a) of the stopper (1) so that the substance is deposited in the reservoir (20) delimited by the closing element (15);

- a subsequent step of positioning of the second body (1b) at least partially within the first body (1a) so that through the positioning a confinement of the reservoir (20) and of the substance is caused within a closed volume, separated from the outer environment.

20. Method according to the previous claim, comprising:

- a step of coupling the stopper (1) with a container (30), wherein, as a result of the coupling, the container (30) is provided with a closed and limited volume, in correspondence of an opening thereof, by the presence of the stopper (1),

- a step of positioning of a perforation or opening element (40, 41, 42) inside the container (30),

- wherein due to the coupling of the stopper (1) with the container (30) and/or with the perforation or opening element (40, 41, 42) a perforation or opening or fracture of the closing element (15) is determined, so that to put the inside of the container (30) in direct communication with the reservoir (20),

- a step of pressure exerting on the second body (1b) of the stopper (1) after or in conjunction of which an axial compression of the stopper (1) is determined, which causes the progressive introduction of the second body (1b) within the first body (1a), the progressive introduction of the second body (1b) within the first body (1a), determining a corresponding progressive reduction of

the volume of the reservoir (20) and a progressive distribution of the substance within the container (30).

21. Method according to claim 20, wherein the perforation or the opening or breaking of the closing element (15) determines at least a partial detachment of the closing element (15) from the first body (1a), of which the closing element (15) is integral part, at least before the perforation or opening or breaking.

22. Kit comprising:

- a releasing stopper (1) according to one or more of the previous claims 1-15;

- an element for the collection and storage of biological and/or microbiological samples (40, 41, 42), comprising a rod (40) with substantially axial development and a swab (42), optionally a flocked swab, made on one end of the rod or to which the rod (40) is solidly and/or rigidly attached; the element of collection and storage of biological and/or microbiological samples (40, 41, 42) is characterized by the fact that the rod (40) is at least partially hollow and is configured to allow the passage of a substance, in particular a fluid, between a first portion of the element for the collection and storage of biological and/or microbiological samples (40, 41, 42) and a second portion in substantial correspondence or proximity of the swab (42) by passing the substance, in particular the fluid, between a cavity (41i) inside the rod (40) and a surface outside the rod (40) itself, where the element the collection and storage of biological and/or microbiological samples (40, 41, 42) is configured and intended to cause the at least partial leakage of a substance (S), in particular a fluid, from the reservoir (20) of the releasing stopper (1) according to one or more of the claims 1-15.

23. Kit according to claim 22, wherein the element for the collection and storage of biological and/or microbiological samples (40, 41, 42), comprises a first transfer duct (40k), optionally a first set of transfer ducts (40k) and at least a

second transfer duct (40f), optionally a second set of transfer ducts (40f); the first transfer duct (40k) and the second transfer duct (40f), optionally the first set of transfer ducts (40k) and the second set of transfer ducts (40f), being in communication with the cavity (41i).

24. Kit according to claim 23, wherein, alternatively:

- the second transfer duct (40f), or the second set of transfer ducts (40f), is arranged at a height at which the swab (42) is present, and/or is overhung and/or surrounded by the swab (42); or

- the second transfer duct (40f), or the second set of transfer ducts (40f), is placed at a different portion of the rod (40) from the portion of the rod (40) at which the swab is present (42).