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(54) Title: OPENING ASSEMBLY FOR BAGS HOUSING CONTAINERS FOR PHARMACEUTICAL USE

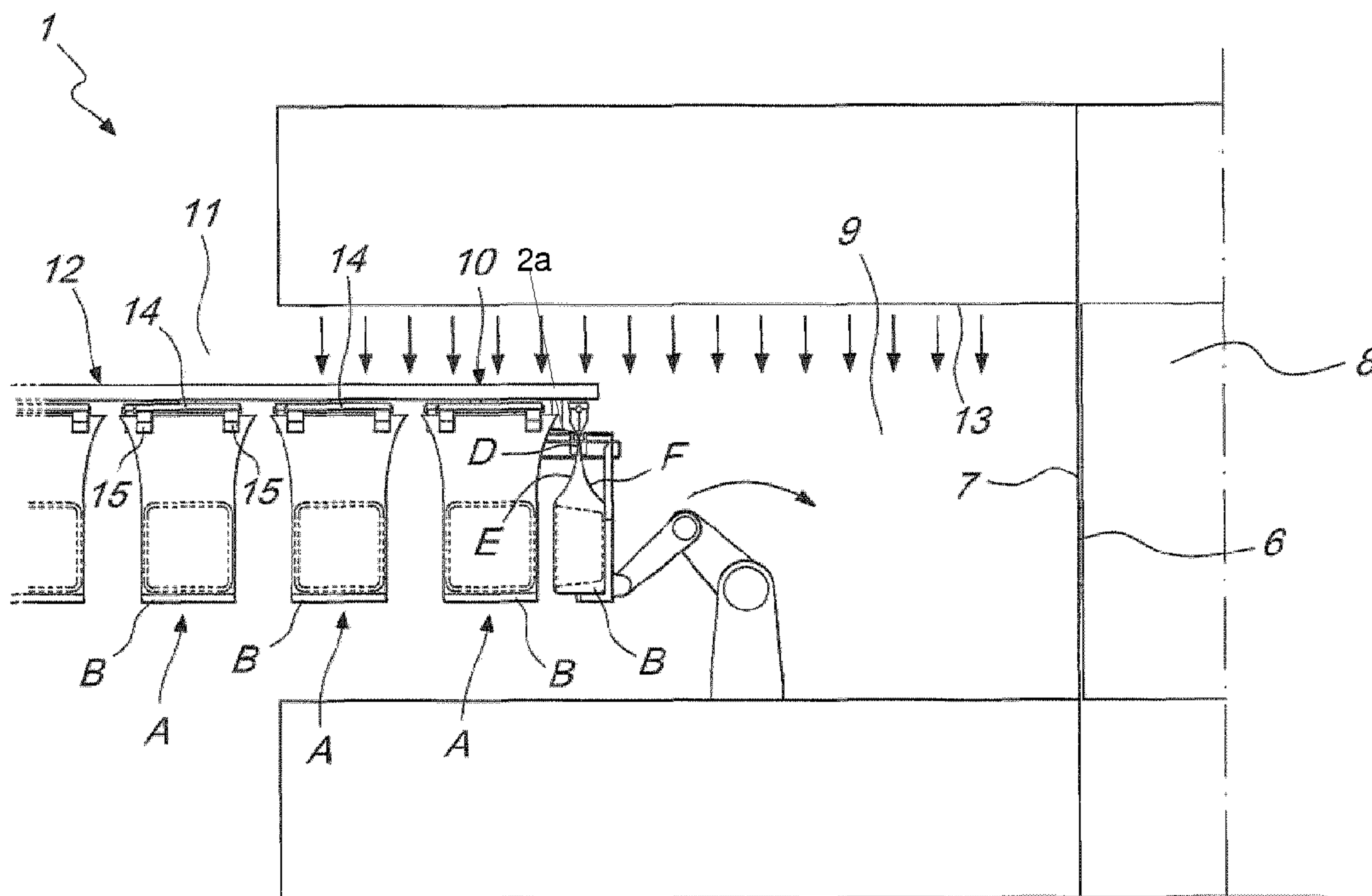


Fig. 2

(57) **Abrégé/Abstract:**

Opening assembly for bags (B) housing containers (A) for pharmaceutical use, comprising at least one clamping mechanism (2) for clamping a portion (C) of said bag (B) spaced apart with respect to an end flap (D) of the bag, said clamping mechanism (2) arranged so as to clamp together sections of opposing sheets (E, F) of said bag (B), and at least one cutting element (2a) for the trimming and the separation of said end flap (D) with respect to said sections of said opposing sheets (E, F) of said bag (B) mutually clamped together by said clamping mechanism (2).

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(54) Title: OPENING ASSEMBLY FOR BAGS HOUSING CONTAINERS FOR PHARMACEUTICAL USE

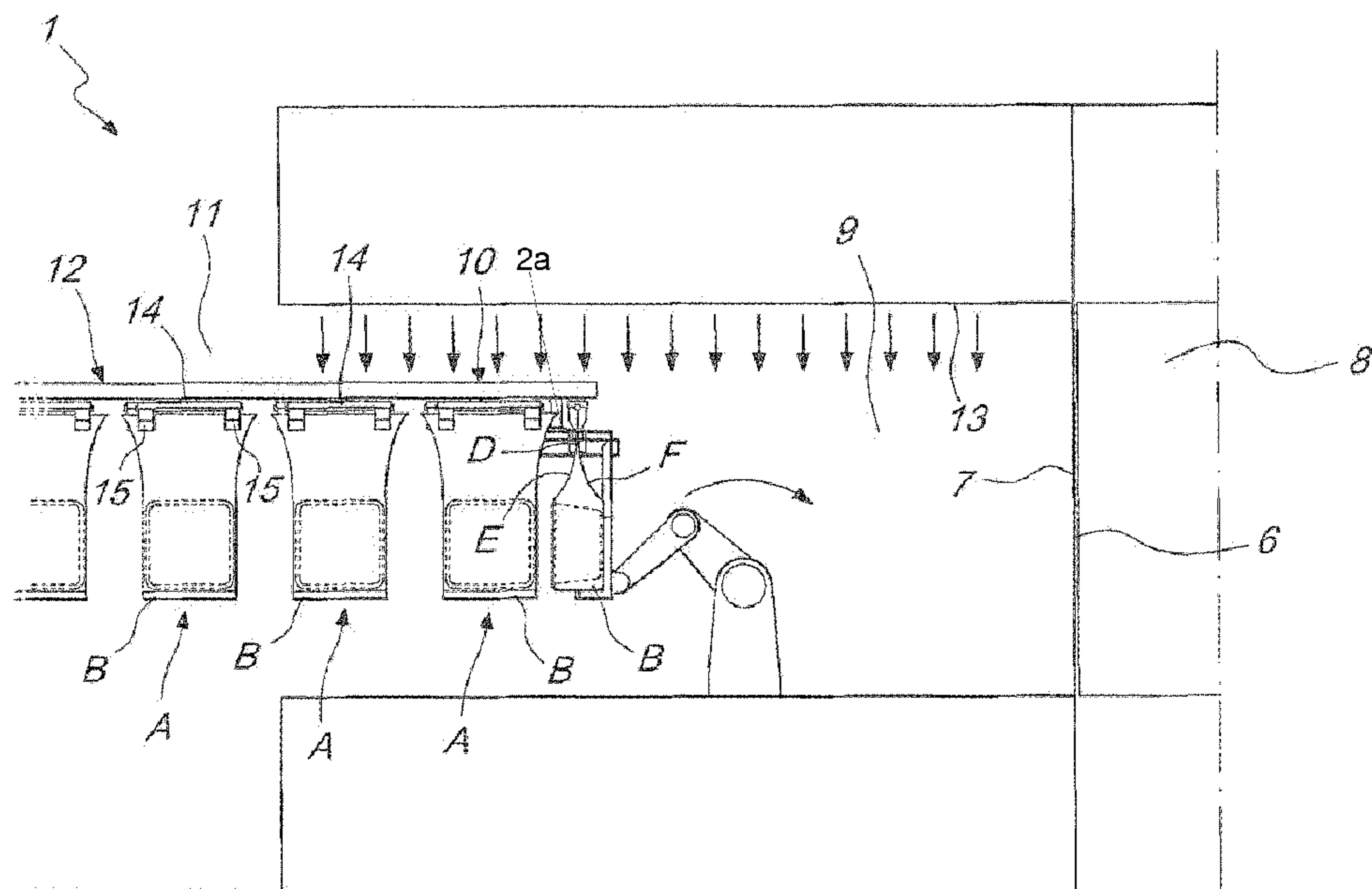


Fig. 2

(57) Abstract: Opening assembly for bags (B) housing containers (A) for pharmaceutical use, comprising at least one clamping mechanism (2) for clamping a portion (C) of said bag (B) spaced apart with respect to an end flap (D) of the bag, said clamping mechanism (2) arranged so as to clamp together sections of opposing sheets (E, F) of said bag (B), and at least one cutting element (2a) for the trimming and the separation of said end flap (D) with respect to said sections of said opposing sheets (E, F) of said bag (B) mutually clamped together by said clamping mechanism (2).

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OPENING ASSEMBLY FOR BAGS HOUSING CONTAINERS FOR PHARMACEUTICAL USE

The present invention relates to an opening assembly for bags housing containers for pharmaceutical use.

- 5 The bag of specific interest is intended for containment and segregation with respect to the outside environment of containers such as vials, bottles, syringes, carpules and the like.

These containers undergo washing and sterilization treatments to ensure that there is no residue inside them (not even dust particles and the like) and
10 to remove any contaminants from their surfaces.

These containers are also normally collected in a nest, which also undergoes similar washing and sterilization treatments.

The nest is, in turn, placed inside a sterile tub with a protective film on top which has the purpose of preventing entrance into the containers (which
15 have an upper opening open towards the outside) of dust or other particles.

The upper edges of the tub (containing protective film, nest and containers) are permanently joined to a sealing film in order to completely isolate the inside of the tub from the outside.

The sealed tub is placed within a bag (generally made of polymeric
20 material) which constitutes a second protective barrier (since the outside of the tub and the sealing film must in any case be sterile).

In this way it is possible to transport the containers so packaged with the guarantee that they will not be subject to involuntary contamination.

Once at the factory where the containers will be filled with specific
25 substances of various types, they will need to be handled in order to be

transported first to the station at which the bag will be opened, and then to the station where the opening film will be removed and finally the filling station for each single container.

These operations will be performed in environments that present a specific
5 particle contamination class (filling operations will be performed in the environment with a lower risk of contamination).

Environments and products are identified by contamination classes defined according to ISO14644/l: the highest contamination class (therefore relating to the environment in which the smallest particle size corresponds at least to
10 that defined as “ISO Class 5” (thus, it could also be an ISO Class 4, 3, 2, 1).

Bag opening operations should be carried out in an environment with a lower risk of contamination compared to the one in which the bags are transported, while the protective film may be removed from the tub only in the environment with the least risk of contamination (i.e., in an environment
15 with ISO contamination class of 5 or lower), imposing additional constraints on the step when removal of the protective film is carried out.

It is specified that the atmosphere inside the bag will also present a very low contamination class (such as, an ISO Class less than or equal to 5).

In any event, bag opening operations are such as to give rise to a risk of
20 contamination (during the cutting step, particles may in fact detach and enter inside the bag, coming into contact with the protective film or the outside of the tub) . The presence of particles on the protective film and/or the outer surface of the tub is particularly risky because removal of the film generally occurs when the tub is already in the environment with the
25 highest contamination class (i.e., ISO 5 Class or lower, thus, with the least

presence of contaminants) and could cause the diffusion of such particles (deposited on the film and/or tub) in that environment.

DE 10 2011 080289 discloses a device for opening a bag according to the prior art.

5 The main aim of the present invention is to solve the problems outlined above, by proposing an opening assembly for bags housing containers for pharmaceutical use capable of cutting the outer bag while preventing particles, in suspension and/or generated during the cutting step, from entering inside the bag.

10 Within the scope of this aim, an object of the invention is to propose an opening assembly for bags housing containers for pharmaceutical use that ensures isolation of the bag's content with respect to the outside environment even after opening the bag.

Another object of the invention is to propose an opening assembly for
15 packaging of containers for pharmaceutical use capable of guaranteeing sterility of the containers transported in the nest present inside the tub, sealed by a protective film, and segregated inside the bag.

It is a further object of this invention to provide an opening assembly for bags housing containers for pharmaceutical use at a low cost and relatively
20 simple, practical implementation and safe application.

This aim and these objects are achieved by an opening assembly for bags housing containers for pharmaceutical use in accordance with Claim 1.

Further characteristics and advantages of the invention will become apparent from the description of a preferred, but not exclusive, embodiment
25 of the opening assembly for bags housing containers according to the

invention, illustrated by way of a non-limiting example, in the accompanying drawings, in which:

Figure 1 shows, in a schematic axonometric view, a portion of an opening assembly for bags housing containers for pharmaceutical use according to the invention;

Figure 2 shows, in a schematic side view, the opening assembly for bags housing containers for pharmaceutical use according to the invention;

With particular reference to the aforementioned figures, it is generally indicated with 1 an opening assembly for bags B housing containers A for pharmaceutical use.

The bag B is generally hermetically sealed and preferably made of polymeric material.

The assembly 1 comprises at least one clamping mechanism 2 to clamp a portion C of the bag B spaced apart (inwardly) with respect to an end flap D of the bag.

The clamping mechanism 2 is arranged so as to clamp together sections of opposing sheets E, F of the bag B.

The assembly 1 further comprises at least one cutting element 2a for the trimming of the end flap D with respect to the portion C defined by the sections of opposing sheets E, F of the bag B mutually clamped together by the clamping mechanism 2.

In this way, it is possible to ensure the clamping of sheets E and F (in particular the portion C on which the clamping mechanism 2 acts) such as to completely segregate and seal the inside of the bag B with respect to the outside environment.

After this step is performed (which ensures that no contamination of the contents of the bag B can occur), the end flap D of the bag B (thus, the opening of the bag B) can then be removed. The transfer to subsequent operating stations where it may be necessary to access the contents of the bag B will occur while the sections of opposing sheets E and F (portion C) are clamped together sealed by the clamping mechanism 2 and thus under such conditions as to prevent contamination of the contents of the bag B.

However, during this transfer, the bag B is in fact already opened (because it is without the end flap D) and thus subsequent access to its contents will not require any operation capable of generating contaminants and/or particles (which may in fact detach during the cutting step) thereby greatly improving the sterility and cleanliness of containers A transported inside the bag B.

In accordance with the present invention, the opening assembly further comprises gripping mechanisms 14 equipped with at least one clamping jaw 15 for gripping the end flap D of the bag B when the bag B hangs from the at least one said jaw 15 of the gripping mechanism 14.

This arrangement is extremely advantageous as it ensures that no undesirable particle buildup can occur on any of the outer surfaces of the bag B: in the traditional type handling units, the bags B lie onto a conveyor belt. The surface of the conveyor belt faces a laminar air flow, but it is not possible to exclude the deposit of particles on the same.

In any case, when the bags B lie on the conveyor belt's surface, the side of the bag B in contact with the conveyor belt is not exposed to the flow and therefore any accumulations of particles (present on the side of the bag B or

on the conveyor belt) will not be affected by the flow which will thus not remove them.

Advantageously, the cutting element 2a is designed to separate the end flap D and is arranged between the gripping mechanisms 14 and the clamping
5 mechanism 2.

Preferably, these gripping mechanisms 14 are associated with a transport device 5.

The transport device 5 in the illustrated example comprises a proximal section 10 arranged in a first zone 9 and a distal section 12 arranged in a
10 second zone 11, wherein the first zone 9 has a higher contamination class and a higher ambient pressure than the second zone.

Said transport device 5 may be a closed loop design and driven by an automatic motor drive unit connected to a control and management processor.

15 In accordance with a preferred embodiment of the present invention, the clamping mechanism 2 is integral with a moveable terminal end 3 of a manipulator 4.

In this way, after clamping the portion C with the clamping mechanism 2 and removing the end flap D with the cutting element 2a, it is possible to
20 remove the bag B (and its contents isolated from the outside environment) from the transport device 5 through the manipulator 4, maintaining the sections of opposing sheets E, F mutually clamped together by means of the clamping mechanism 2, and deliver them to a possible downstream operating station.

25 It is considered useful to specify that the manipulator 4 can advantageously

move between at least two end configurations.

A first configuration whereby the bag B is removed from the transport device 5 for the clamping of said opposing sheets E, F with the clamping mechanism 2; and a second alignment configuration whereby the bag B is
5 brought in proximity to an opening 6 defined on a separation wall 7 separating the first zone 9 from a compartment 8 with a higher contamination class and higher ambient pressure compared to the first zone 9.

By way of example, it is specified that inside the compartment 8, an ISO
10 contamination class of “5” or lower, more “safe” compared to the one in the first zone 9, could be established.

With particular reference to an embodiment capable of meeting the stringent regulatory requirements in force concerning the packaging of drugs and even define improved safety standards in connection with the
15 same, the first zone 9 within which the manipulator 4 operates and in which the proximal section 10 of the transport device 5 is located, has a higher contamination class and a higher ambient pressure compared to the second zone 11 in which the distal section 12 of the transport device 5 is located.

In practice, an operating condition will occur whereby the transport of
20 packaging A will be carried out in ambient conditions with a less stringent contamination class (i.e, ISO Class 6 or ISO Class 7), the cutting of the end flap D and thus the opening of the bag B will occur in ambient conditions with an intermediate contamination class (according to the previous example, in ISO Class 6 or ISO Class 6+ or ISO Class 5 respectively),
25 while the extraction of the contents of the bag B will only occur in the

compartment 8 in which there is a higher contamination class (according to the previous example, ISO Class 5).

According to a particularly efficient and easily programmable version, the manipulator 4 can be an anthropomorphic-type robot.

- 5 In the first zone 9, there is preferably arranged at least one dispenser of a gas flow intended to flow over the proximal section 10 of the transport device 5, the bag B transported along the end section 10 and the manipulator 4.

Such gas flow will provide the necessary overpressure in the first zone 9,
10 with respect to the second zone 11 in which the distal section 12 of the transport device 5 is located so as to prevent access to the first zone 9 of particles and/or contaminants present in suspension in the air in the second zone 11.

It is specified that, preferably, the gas flow present in the first zone 9 will
15 be of the laminar type.

With reference to an embodiment that is simple to implement, it should be noted that the gas relating to such flow may be air (other types of gas such as inert gas, nitrogen and the like are not excluded).

The transport device 5 thus adopted allows all surfaces of each bag B to be
20 invested by the gas, favoring the detachment of any particles accumulated thereupon, while hindering the deposit of any other particles present in suspension in the air of the particular environment in question.

The operation of the present invention is precisely outlined in the steps listed below.

- 25 In a first step, it is necessary to have a portion C of the bag B, spaced apart

(inwardly) relative to an end flap D, in alignment with a clamping mechanism 2.

Subsequently, in a second step, it will be necessary to clamp, with the clamping mechanism 2, sections of opposing sheets E, F of the bag B, that is, the portion C, isolating the contents of the part of bag B that is downstream with respect to the clamping mechanism 2.

A final step of the process involves trimming by means of a cutting element 2a the end flap D with respect to the portion C corresponding to the sections of opposing sheets E, F of the bag B mutually clamped together by the clamping mechanism 2.

Preferably, the process involves aligning the portion C of bag B to the clamping mechanism 2, keeping it sealed by isolating the contents of the bag B from the outside environment, at a subsequent operating station, so that the containers A placed inside the bag B remain isolated from the outside environment even after the trimming.

Advantageously, the present invention solves the problems outlined above, by proposing an opening assembly 1 for bags housing containers for pharmaceutical use, preventing particles, in suspension and/or generated during the cutting step, from entering inside the bag B.

Effectively, the opening assembly 1 according to the invention guarantees the isolation of the contents of the bag B from the outside environment even after cutting the bag B.

Appropriately, the opening assembly 1 according to the invention is capable of guaranteeing the sterility of the containers transported in the nest inside the tub, sealed by a protective film, and segregated inside the bag B.

Beneficially, the opening assembly 1 according to the invention is relatively simple and practical to implement, and also entails contained costs: these features make the unit 1 an innovative and safe application.

The invention, thus conceived, is susceptible to numerous modifications
5 and variants all falling within the scope of the inventive concept; moreover, all of the details may be replaced by other technically equivalent elements.

In the sample embodiments illustrated, individual features, described in relation to specific examples, are in fact interchangeable with other different features, existing in other embodiments.

10 In practice, the materials used, as well as their sizes, may be of any kind according to the requirements and the state of the art.

CLAIMS

1. Opening assembly for bags (B) housing containers (A) for pharmaceutical use, comprising at least one clamping mechanism (2) for clamping a portion (C) of said bag (B) and at least one cutting element (2a)
5 **characterized in that** said clamping mechanism (2) is arranged to clamp together sections of opposing sheets (E, F) of said bag (B) which are spaced apart with respect to an end flap (D) of the bag (B) **and in that** said at least one cutting element (2a) is arranged and configured for the trimming and the separation of said end flap (D) protruding with respect to said sections
10 of said opposing sheets (E, F) of said bag (B) mutually clamped together by said clamping mechanism (2).
2. Opening assembly according to Claim 1, comprising gripping mechanisms (14) equipped with at least one clamping jaw (15) for gripping said end flap (D) of the bag (B), said bag (B) hanging from the at least one
15 jaw (15) of the gripping mechanism (14).
3. Opening assembly, according to Claim 2, wherein said gripping mechanisms (14) are associated to a transport device (5).
4. Opening assembly according to Claim 3, wherein said transport device (5) comprises a proximal section (10) arranged in a first zone (9) and a
20 distal section (12) arranged in a second zone (11), wherein the first zone (9) has a higher contamination class and a higher ambient pressure than the second zone (11).
5. Opening assembly according to Claim 3 or 4, wherein said transport device (5) has a closed loop configuration and is driven by an automatic
25 drive unit connected to a control and management processor.

6. Opening assembly according to any one of the preceding Claims 2 to 5, wherein said cutting element (2a) is arranged between said gripping mechanisms (14) and said clamping mechanism (2), when the end flap (D) is separated from said sections of opposing sheets (E, F) clamped by the
5 clamping mechanism (2).

7. Opening assembly according to any one of the preceding Claims, wherein said clamping mechanism (2) is integral with a movable terminal end (3) of a manipulator (4).

8. Opening assembly according to Claim 7, wherein said manipulator (4) is
10 an anthropomorphic-type robot.

9. Opening assembly according to Claim 7 or 8, wherein said manipulator (4) is movable between at least two end configurations, a first configuration wherein the bag (B) is removed from said transport device (5) for the clamping of said opposing sheets (E, F) with said clamping mechanism (2),
15 and a second configuration wherein the bag (B) is brought in proximity to an opening (6) defined on a separation wall (7) separating said first zone (9) from a compartment (8) with a higher contamination class and higher ambient pressure compared to the first zone (9).

10. Opening assembly, according to Claim 9, wherein in said first zone (9),
20 there is arranged at least one dispenser of a gas flow intended to flow over the proximal section (10) of said transport device (5), said bag (B) transported along said end section (10) and said manipulator (4) located in the first zone (9).

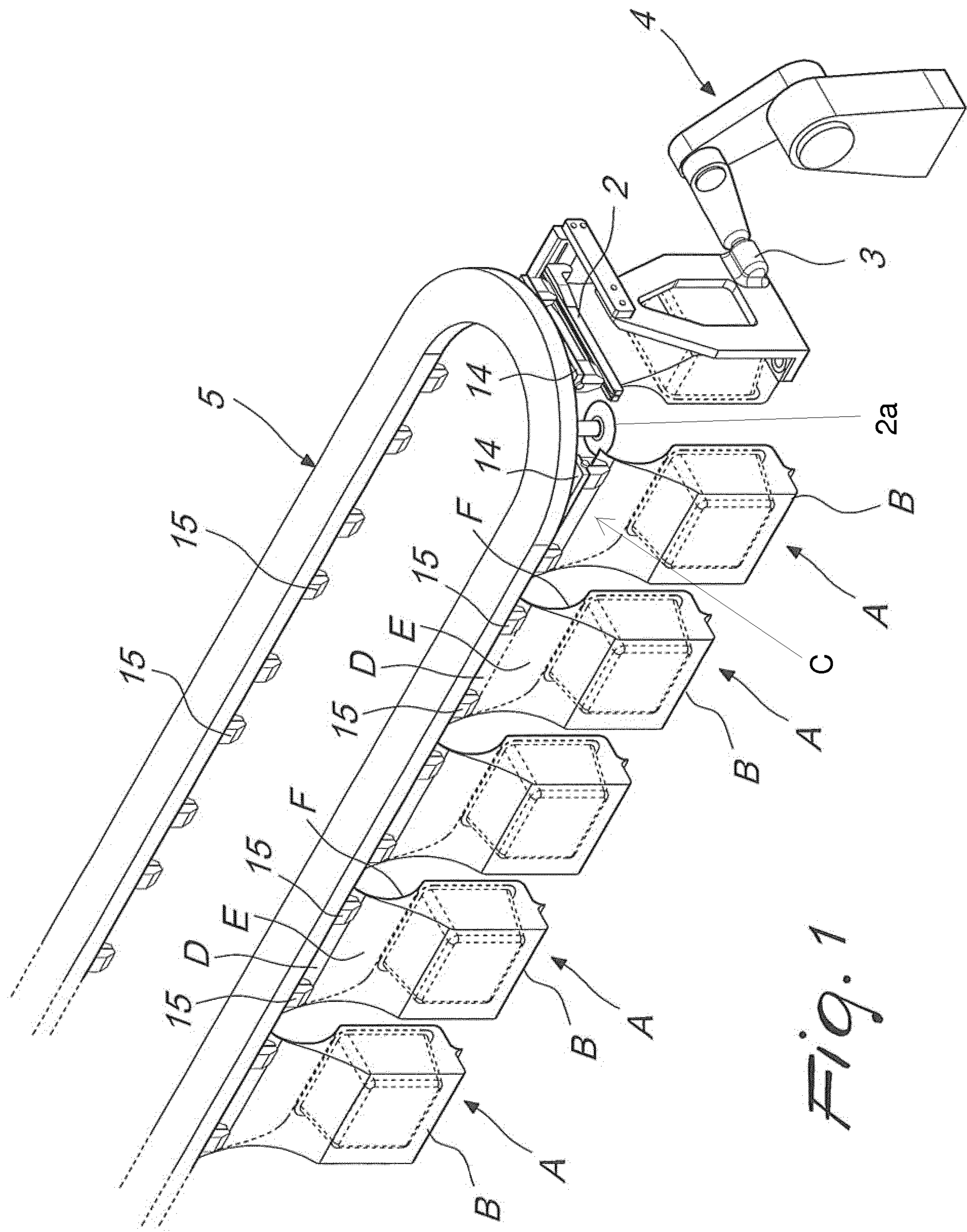
11. Opening assembly according to Claim 10, wherein said gas flow is of
25 the laminar type.

12. Method for opening bags (B) housing containers (A) for pharmaceutical use, comprising the steps of:

- arranging a portion (C) of said bag (B) spaced apart with respect to an end flap (D) in alignment with a clamping mechanism (2);
- 5 – clamping together sections of opposing sheets (E, F) of said bag (B) with said clamping mechanism (2);
- trimming and separating, by means of a cutting element (2a), said end flap (D) with respect to said sections of said opposing sheets (E, F) of said bag (B) mutually clamped together by said clamping mechanism (2).

10 13. Method according to Claim 12, further comprising the step of aligning the portion of bag (B) clamped by said clamping mechanism (2) at a subsequent operating station.

14. Method according to Claim 12 or 13, wherein the clamping of the bag (B) with the clamping mechanism (2) keeps said sections of opposing
15 sheets (E, F) clamped together, so that the containers (A) placed inside of the bag (B) remain isolated from the outside environment even after trimming.



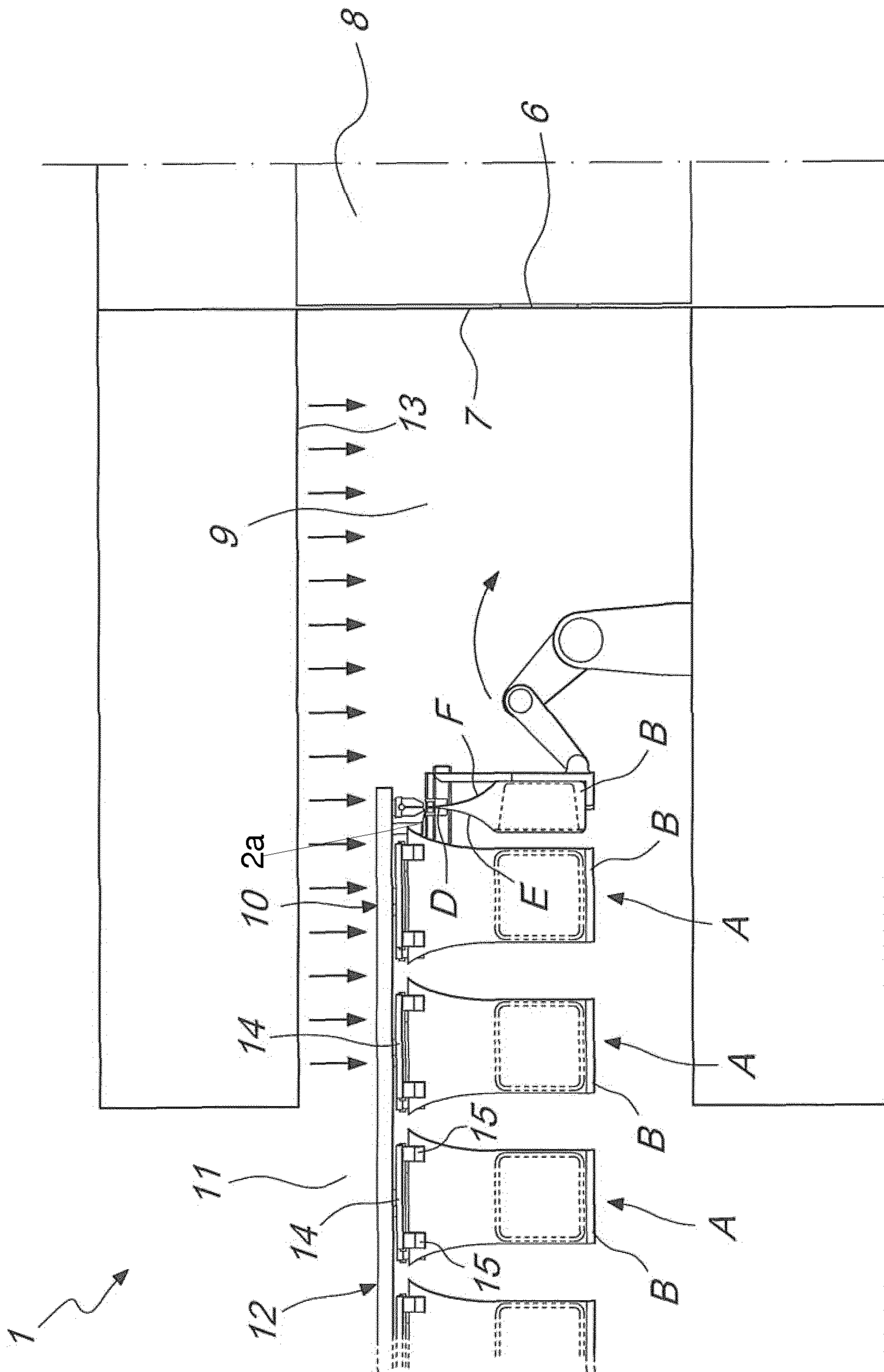


Fig. 2

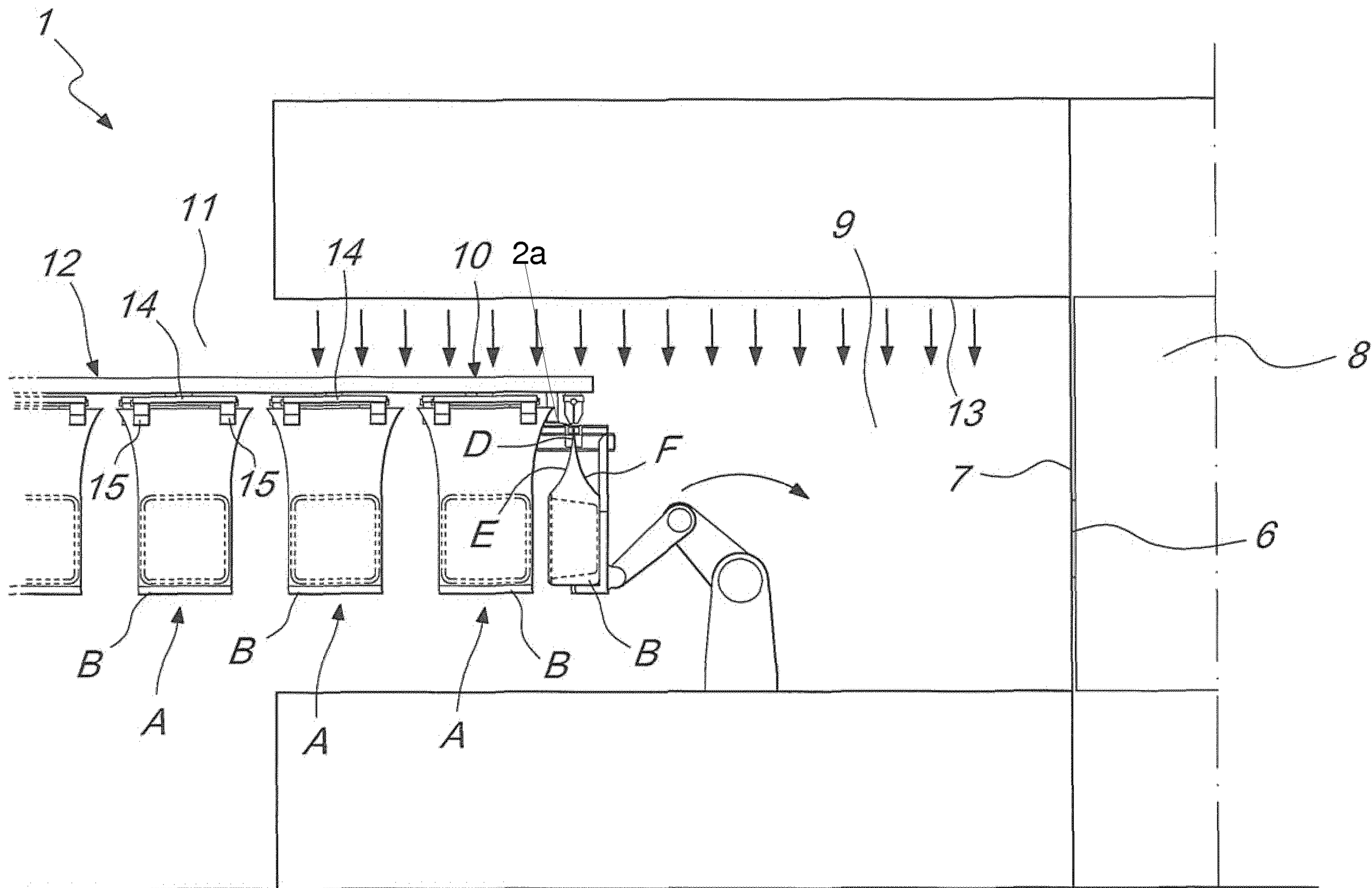


Fig. 2