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(54) PACKAGING SYSTEM FOR PHARMACEUTICAL PRODUCTS, CHEMICAL PRODUCTS, BIOCIDAL PRODUCTS AND THE LIKE

(57) A packaging system (1) for pharmaceutical products, chemical products, biocidal products and the like, which comprise a forming station (2) for a continuous sheet (3) provided with a plurality of receptacles, an assembly (5) for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like inside each receptacle, an apparatus (6) for coupling a film to a surface of the sheet (3) in order to close the receptacles, and a cutting unit (7) for cutting the sheet (3a) closed by the film according to specific formats.

The assembly (5) for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like inside each receptacle and the apparatus (6) for coupling a film on a surface of the sheet (3) in order to close the receptacles are contained inside a clean room (9) with a controlled atmosphere. At least one apparatus chosen from the forming station (2) for a continuous sheet (3) provided with a plurality of receptacles and the cutting unit (7) for cutting the sheet closed by the film (3a) according to specific formats faces toward and is proximate to the clean room (9), outside it.

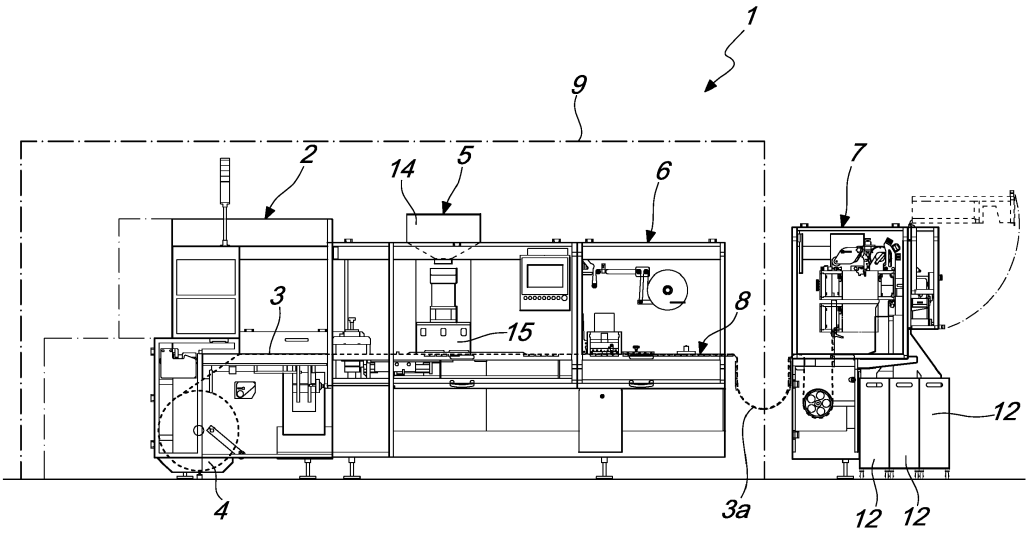

Fig. 1

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Description

[0001] The present invention relates to a packaging system for pharmaceutical products, chemical products, biocidal products and the like.

[0002] Some types of products in the pharmaceutical sector (but also some biocidal products and even, in general, several types of chemical products) need to be packaged separately for the purpose of preventing contamination phenomena.

[0003] In particular it is known to use packaging in blister packs of capsules, pastilles and tablets (generically of small solid blocks, pre-dosed with product) and/or of discrete quantities of powders in order to make it possible to separate each individual element from the others present in the same package.

[0004] Blister packs are sheets (generally made of polymeric or metallic or composite material) provided with a plurality of receptacles distributed on their surface; each receptacle is designed to accommodate an individual element (pastille, pill, tablet, generic solid block); the sheet of receptacles is covered with a closing sheet that also hermetically closes each receptacle and its contents (i.e. the pastille, pill, tablet and/or the generic solid block).

[0005] The packaging operations (thermo-forming of the receptacles on the sheet, insertion of the respective individual element into each receptacle, hermetic closure via the respective sheet, and cutting to format of each blister pack) must be carried out in a protected and segregated environment known, in the sector, as a "clean room".

[0006] In these rooms, by virtue of specific methods of controlling and conditioning the atmosphere, an extremely low content of microparticles of dust in suspension can be achieved.

[0007] Furthermore it should be noted that the pharmaceutical industry (and in general all of the chemical industry) has developed increasingly powerful active ingredients and laboratory products that require very careful handling in order to prevent intoxication of the operators responsible for the production and the packaging thereof.

[0008] The adoption of isolated environments and of clean rooms therefore constitutes a solution to this additional type of problems as well (necessary to protect the operators responsible for production and packaging).

[0009] Providing, installing and maintaining a clean room in service all have very high costs which are directly proportional to the dimensions of the clean room.

[0010] Furthermore, any malfunction of the machines located inside the clean room implies shutting down production and discarding the production queue.

[0011] To resolve the malfunction, it is then necessary for the technical assistance staff to enter the clean room (with consequent contamination thereof and of all the semi-finished products contained in it) and subsequently to perform a step of remediation of the internal atmosphere before restarting production.

[0012] The aim of the present invention is to solve the abovementioned drawbacks, by providing a packaging system for pharmaceutical products, chemical products, biocidal products and the like that makes it possible to reduce the costs of providing, installing and maintaining the respective clean room.

[0013] Within this aim, an object of the invention is to provide a packaging system for pharmaceutical products, chemical products, biocidal products and the like that facilitates the operations of ordinary and extraordinary maintenance of the machines that constitute it.

[0014] Another object of the invention is to provide a packaging system for pharmaceutical products, chemical products, biocidal products and the like that minimizes the effects of a machine shutdown caused by a malfunction.

[0015] Another object of the invention is to provide a packaging system for pharmaceutical products, chemical products, biocidal products and the like that makes it possible to preserve and use the production queue, when a malfunction occurs.

[0016] Another object of the present invention is to provide a packaging system for pharmaceutical products, chemical products, biocidal products and the like that is low cost, easily and practically implemented and safe in use.

[0017] This aim and these and other objects which will become better apparent hereinafter are achieved by a packaging system for pharmaceutical products, chemical products, biocidal products and the like, of the type comprising a forming station for a continuous sheet provided with a plurality of receptacles, an assembly for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like inside each receptacle, an apparatus for coupling a film to a surface of said sheet in order to close said receptacles, and a cutting unit for cutting said sheet closed by said film according to specific formats, characterized in that said assembly for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like inside each receptacle and said apparatus for coupling a film to a surface of said sheet in order to close said receptacles are contained within a clean room with a controlled atmosphere; at least one apparatus chosen from said forming station for a continuous sheet provided with a plurality of receptacles and said cutting unit for cutting said sheet closed by said film according to specific formats faces toward and is proximate to said clean room, outside it.

[0018] Further characteristics and advantages of the invention will become more apparent from the detailed description that follows of a preferred, but not exclusive, embodiment of the packaging system for pharmaceutical products, chemical products, biocidal products and the like according to the invention, which is illustrated by way of non-limiting example in the accompanying drawings wherein:

Figure 1 is a schematic front view of a first embodiment of the packaging system for pharmaceutical products, chemical products, biocidal products and the like according to the invention;

Figure 2 is a schematic view from above of the system of Figure 1;

Figure 3 is a schematic front view of a second embodiment of the packaging system for pharmaceutical products, chemical products, biocidal products and the like according to the invention;

Figure 4 is a schematic view from above of the system of Figure 3.

[0019] With reference to the figures, the reference numeral 1 generally designates a packaging system for pharmaceutical products, chemical products, biocidal products and the like.

[0020] The packaging system 1 comprises a forming station 2 for a continuous sheet provided with a plurality of receptacles.

[0021] In particular the station 2 comprises a spool on which a ribbon 4 is gathered which is entrained toward an operating area where it is subjected to deformation (through the application of thermal and/or mechanical stresses and/or combinations thereof) in order to provide a plurality of distributed receptacles and form the continuous sheet provided with receptacles.

[0022] The system 1 further comprises an assembly 5 for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like into each receptacle of the sheet.

[0023] The deposition of the rations (i.e. capsules, pastilles, tablets, pills and other discrete elements and/or powders of any form and/or granulometry) into the receptacles can be achieved solely by falling (gravity) or by using methods that are more precise and complex (for example through means for picking and placing, in use in the sector).

[0024] The system 1 further comprises an apparatus 6 for coupling a film on a surface of the sheet 3 in order to close the receptacles.

[0025] Downstream of the system 1 there is a cutting unit 7 for cutting the stratified combination 8 constituted by the sheet 7 closed by the respective film so as to contain and segregate the rations in the receptacles.

[0026] The cutting operations executed by the unit 7 will be such as to generate individual packages (blister packs) that have specific predefined and standardized formats.

[0027] According to the invention, the assembly 5 (designed to deposit the pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like into each receptacle) and the apparatus 6 (which carries out the coupling of the film on a surface of the sheet in order to close the receptacles) are contained inside a clean room 9 with a controlled atmosphere.

[0028] In such context, the system 1 according to the invention advantageously entails that at least one apparatus chosen from the forming station 2 and the cutting unit 7 can face toward and be proximate to the clean room 9, but outside it.

[0029] Such architecture of the system 1 is particularly advantageous and innovative because it makes it possible to execute all the necessary operations to handle pharmaceutical products, chemical products, biocidal products and the like inside the clean room 9 (therefore isolating these products from the outside environment with consequent elimination of all risks of contamination thereof and of intoxication of the operators responsible for conducting and controlling the system), while minimizing the dimensions of the clean room 9 itself, since the forming station 2 and/or the cutting unit 7 will be located outside the chamber 9.

[0030] In traditional systems the forming station 2 and the cutting unit 7 are located inside the clean room 9 and therefore the clean room must have a volume that is sufficient to accommodate them.

[0031] Clearly the maintenance of the controlled atmosphere inside the clean room 9 (of small dimensions) of the system 1 according to the invention will be simpler than with traditional systems, in which the large dimensions of the respective clean rooms require complicated and expensive (also in terms of running costs) methods of controlling and managing the internal atmosphere.

[0032] Furthermore, the arrangement of the station 1 or of the unit 7 (or of both) outside the clean room 9 reduces the probability of having to intervene for maintenance operations inside the clean room 9 itself.

[0033] In fact the clean room 9 accommodates only the assembly 5 for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like and the apparatus for coupling the film 6 for closing (optionally also the forming station 2), thus reducing the risk that the portion of the system in which the malfunction occurs could be inside the clean room 9.

[0034] In addition the cutting unit 7 is certainly the portion of the system that requires the most frequent maintenance, since the cutting means can be subject to wear and tear and therefore these means need to be replaced and/or restored.

[0035] It should be noted that, if the station 2 is outside of the clean room 9, such clean room 9 will conveniently comprise at least one respective opening 10 for the entry of the sheet provided with receptacles 3.

[0036] In order to ensure the correct control of the atmosphere inside the clean room 9, an internal pressure is established in the chamber 9 which is greater than the pressure of the outside environment, in order to prevent the entry of contaminants at the point of entry of the sheet 3.

[0037] If the cutting unit 7 is located outside the clean room 9, then it will conveniently comprise at least one passage opening 11 for the exit of the sheet 3a closed by the film.

[0038] In this case too, the atmosphere inside the clean room 9 will be positively maintained at a pressure greater

than that of the outside environment in order to prevent the entry of contaminants at the point of exit of the closed sheet 3a.

[0039] With particular reference to an embodiment of undoubted practical and applicative interest, upstream of the cutting unit 7 a spool can be installed for winding the closed sheet 3a.

[0040] In this manner it will be possible to execute the collection of the closed sheet 3a at steps involving interruptions of operation, malfunctions and/or breakdowns of the cutting unit 7.

[0041] This means that, even after a malfunction of the cutting unit (which occurs during production) it will be possible to not interrupt production and to store the closed sheet 3a in the aforementioned spool and to then proceed later (once the cutting unit 7 has been restored) to subdivide the closed sheet 3a into single packages (blister packs) even while the part of the system 1 that is upstream is switched off.

[0042] It is convenient to note that the cutting unit 7 will profitably comprise, downstream, at least one container 12 for collecting processing waste, such as defective packages (blister packs), offcuts and the like.

[0043] The unit 7 will further comprise, at its exit, means for transferring the correctly manufactured packages (blister packs) of predefined format to further work machines that are adapted for storage or for secondary packaging or for other operating steps.

[0044] As already mentioned above, the clean room 9 will positively have an internal volume that is appreciably smaller than that provided in traditional systems and substantially linked to the encumbrances of the group constituted by the forming station 2, by the assembly for deposition 5 and by the apparatus for coupling 6: keeping the cutting unit 7 outside will therefore make it possible to carry out operations to maintain it without contaminating anything inside the clean room 9.

[0045] With particular reference to an additional embodiment of undoubted applicative interest, the clean room 9 can have an internal volume that is much smaller than in traditional systems and substantially linked to the encumbrances of the group constituted by the assembly 5 for deposition and by the apparatus 6 for coupling.

[0046] In this second case, also keeping the forming station 2 outside will contribute to reducing the risk of malfunction and to minimizing the internal volume of the clean room 9.

[0047] The forming station 2 for a continuous sheet provided with a plurality of receptacles can conveniently be accommodated inside a second room 13 with a controlled atmosphere, which is separate from the clean room 9.

[0048] The second room 13 can also circulate purified air similar to the clean room 9 and in this case the advantage of subdividing the various parts of the system 1 into two similar (but smaller) chambers lies in the possibility of carrying out targeted maintenance interventions, excluding the possibility of contaminating all parts of the system 1. Furthermore the rooms of small dimensions have generally lower production and installation costs, not least due to the greater ease of transporting smaller components that precedes their installation.

[0049] The possibility is not ruled out that the second room 13 can have a less rigorous control of the atmosphere with respect to the control maintained in the clean room 9 and this will determine a further reduction in the running costs with respect to traditional systems.

[0050] It should furthermore be noted that the assembly 5 for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like can advantageously comprise an upper hopper 14 for the temporary accommodation of a plurality of rations (to be inserted subsequently into the receptacles) and a distribution and dispensing element 15, which is provided with means for delivering at least one block inside a respective receptacle.

[0051] It should be noted that the clean room 9 and the second room 13 with a controlled atmosphere can profitably comprise a respective forced ventilation circuit for establishing a laminar air flow directed from the top of the room 9, 13 to the floor thereof, so as to ensure that no deposits of dust and/or contamination can occur.

[0052] Along the forced ventilation circuit there will be adapted filters which will be adapted to eliminate particles and dust.

[0053] The arrangement of the format cutting unit 7 for the packages further makes it possible to arrange the boxing machines (for the secondary packaging) downstream of the system 1, without it being necessary to also install these in an area with a controlled atmosphere, as happens in some implementation solutions in the background art.

[0054] This contrivance ensures a considerable containment of the production costs of the end product (i.e. the packages (blister packs) conveniently accommodated inside a respective box).

[0055] Advantageously the present invention solves the abovementioned problems, by providing a packaging system 1 for pharmaceutical products, chemical products, biocidal products and the like that makes it possible to reduce the costs of providing, installing and maintaining the related clean room 9.

[0056] By providing a clean room 9 of smaller dimensions, it is evident that it will have lower production, installation and running costs than traditional systems: the system 1 according to the invention in any case ensures that levels of safety against contamination of the products being packaged and levels of protection of staff from risk of intoxication are kept at least analogous to (and potentially much higher than) those of the traditional systems.

[0057] Conveniently the system 1 facilitates the operations of ordinary and extraordinary maintenance of the machines that constitute it.

[0058] In fact all maintenance interventions that need to be carried out on machines that are located outside the clean room 9 will not require remediation operations

of the atmosphere inside the chamber 9, and are therefore more rapid and less expensive than the operations currently required in systems of the conventional type.

[0059] Usefully the system 1 minimizes the effects of machine shutdowns caused by a malfunction.

[0060] In the event of malfunction of the cutting unit 7, it will in fact be possible to collect the closed sheet 3a in the abovementioned storage spool without interrupting the packaging operations: it will be possible to proceed with the operations to cut the packages (blister packs) at a later time.

[0061] Profitably the system 1 according to the invention makes it possible to preserve and use the production queue, when a malfunction occurs.

[0062] Such advantage is particularly important when it is considered that by contrast, in systems according to the known art, it is generally necessary to discard the entire production queue in the event of a malfunction.

[0063] The system 1 according to the invention therefore makes it possible to reduce the packaging operations inside the clean room 9 (in a protected atmosphere) to those strictly necessary for the protection of the product, by separating the operations to the point where the operations in direct contact with the product to be packaged can be isolated. In this manner the clean room 9 is optimized for just the operations necessary and the portion of the system 1 to be enclosed in a protective atmosphere is shorter than in traditional systems.

[0064] It should be pointed out that the passage between the clean room 9 and the non-aseptic room (i.e. where the cutting unit 7 is located) is better controlled and controllable because it is simpler to manage a continuous closed sheet 3a than it is to manage a plurality of individual packages (blister packs) that are laterally adjacent and aligned. In fact, by exiting only with a continuous closed sheet 3a from the clean room 9 it is much simpler to obtain the separation of the primary packaging area from the secondary packaging area.

[0065] Furthermore the flows that bring the products into the clean room 9 and the flow that brings the continuous closed sheet 3a of the packaged product outside are unidirectional and do not require any dedicated mechanical conveyance element (i.e. no belt, chain or any feeder is needed) which if present would pass from the controlled area to the uncontrolled area and vice versa with each operation cycle. By separating the cutting unit 7 from the clean room 9, the passage will occur of only the continuous closed (and therefore protected) sheet 3a and, at the same time, the risks for the operators of the other areas of production will be eliminated. In addition to the cutting unit 7, the feeding of the sheet 3 and the associated thermoforming (carried out in the station 2) can also be separated (therefore carried out outside the clean room 9).

[0066] The possibility is also not ruled out of carrying out optional initial processes to print and/or encode the covering film outside the clean room, since only its coupling to the sheet 3 needs to be carried out inside the clean room 9 by the assembly 6.

[0067] Positively the present invention makes it possible to provide a packaging system 1 that is easily and practically implemented and which is low-cost: the characteristics highlighted make the assembly 1 according to the invention an innovation that is certain to be safe in use.

[0068] The invention, thus conceived, is susceptible of numerous modifications and variations, all of which are within the scope of the appended claims. Moreover, all the details may be substituted by other, technically equivalent elements.

[0069] In the embodiments illustrated, individual characteristics shown in relation to specific examples may in reality be interchanged with other, different characteristics, existing in other embodiments.

[0070] In practice, the materials employed, as well as the dimensions, may be any according to requirements and to the state of the art.

[0071] The disclosures in Italian Patent Application No. 102019000021762 from which this application claims priority are incorporated herein by reference.

[0072] Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly, such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

Claims

1. A packaging system for pharmaceutical products, chemical products, biocidal products and the like, of the type comprising a forming station (2) for a continuous sheet (3) provided with a plurality of receptacles, an assembly (5) for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like inside each receptacle, an apparatus (6) for coupling a film on a surface of said sheet (3) in order to close said receptacles, and a cutting unit (7) for cutting said sheet (3a) closed by said film according to specific formats, **characterized in that**:

    - said assembly (5) for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like inside each receptacle and said apparatus (6) for coupling a film to a surface of said sheet (3) in order to close said receptacles are contained within a clean room (9) with a controlled atmosphere;
    - at least one apparatus chosen from said forming station (2) for a continuous sheet (3) provided with a plurality of receptacles and said cutting unit (7) for cutting said sheet (3a) closed by said film according to specific formats faces toward

and is proximate to said clean room (9), outside it.

2. The packaging system according to claim 1, **characterized in that** said clean room (9) comprises at least one respective opening (10) for the entry of said sheet (3) provided with receptacles, the atmosphere inside said clean room (9) being at a higher pressure than the outside environment in order to prevent the entry of contaminants at the point of entry of said sheet (3).

3. The packaging system according to 1, **characterized in that** said clean room (9) comprises at least one passage opening (11) for the exit of said sheet (3a) closed by said film, the atmosphere inside said clean room (9) being at a higher pressure than the outside environment in order to avoid the entry of contaminants at the point of exit of said closed sheet (3a).

4. The packaging system according to claim 1, **characterized in that** upstream of said cutting unit (7) for cutting said closed sheet (3a) it is possible to install a spool for winding said sheet closed by said film (3a), which is designed to collect said sheet closed by said film (3a) at steps involving interruptions of operation, malfunctions and/or breakdowns of said cutting unit (7).

5. The packaging system according to claim 1, **characterized in that** said cutting unit (7) comprises downstream at least one container (12) for collecting processing waste, such as defective packages (blister packs), offcuts and the like, said unit (7) comprising means for transferring the correctly manufactured packages (blister packs) of predefined format toward further work machines.

6. The packaging system according to claim 1, **characterized in that** said clean room (9) has an internal volume that is substantially complementary to the space occupations of the assembly constituted by said forming station (2) for a continuous sheet (3) provided with a plurality of receptacles, said deposition assembly (5), and said apparatus (6) for coupling a film on a surface of said sheet (3).

7. The packaging system according to claim 1 and as an alternative to claim 6, **characterized in that** said clean room (9) has an internal volume that is substantially complementary to the space occupations of the assembly constituted by said deposition assembly (5) and said apparatus (6) for coupling a film on a surface of said sheet (3).

8. The packaging system according to one or more of the preceding claims, **characterized in that** said forming station (2) for a continuous sheet (3) provided with a plurality of receptacles is accommodated inside a second room (13) with a controlled atmosphere, which is separate from said clean room (9).

9. The packaging system according to one or more of the preceding claims, **characterized in that** said assembly (5) for depositing pre-dosed rations of pharmaceutical products, chemical products, biocidal products and the like comprises an upper hopper (14) for accommodating a plurality of said rations and a distribution and dispensing element (15), which is provided with means for delivering at least one said block inside a respective receptacle.

10. The packaging system according to one or more of the preceding claims, **characterized in that** said clean room (9) and said second room (13) with a controlled atmosphere comprise a respective forced ventilation circuit for establishing a laminar air flow directed from the top of the room (9, 13) to the floor thereof.

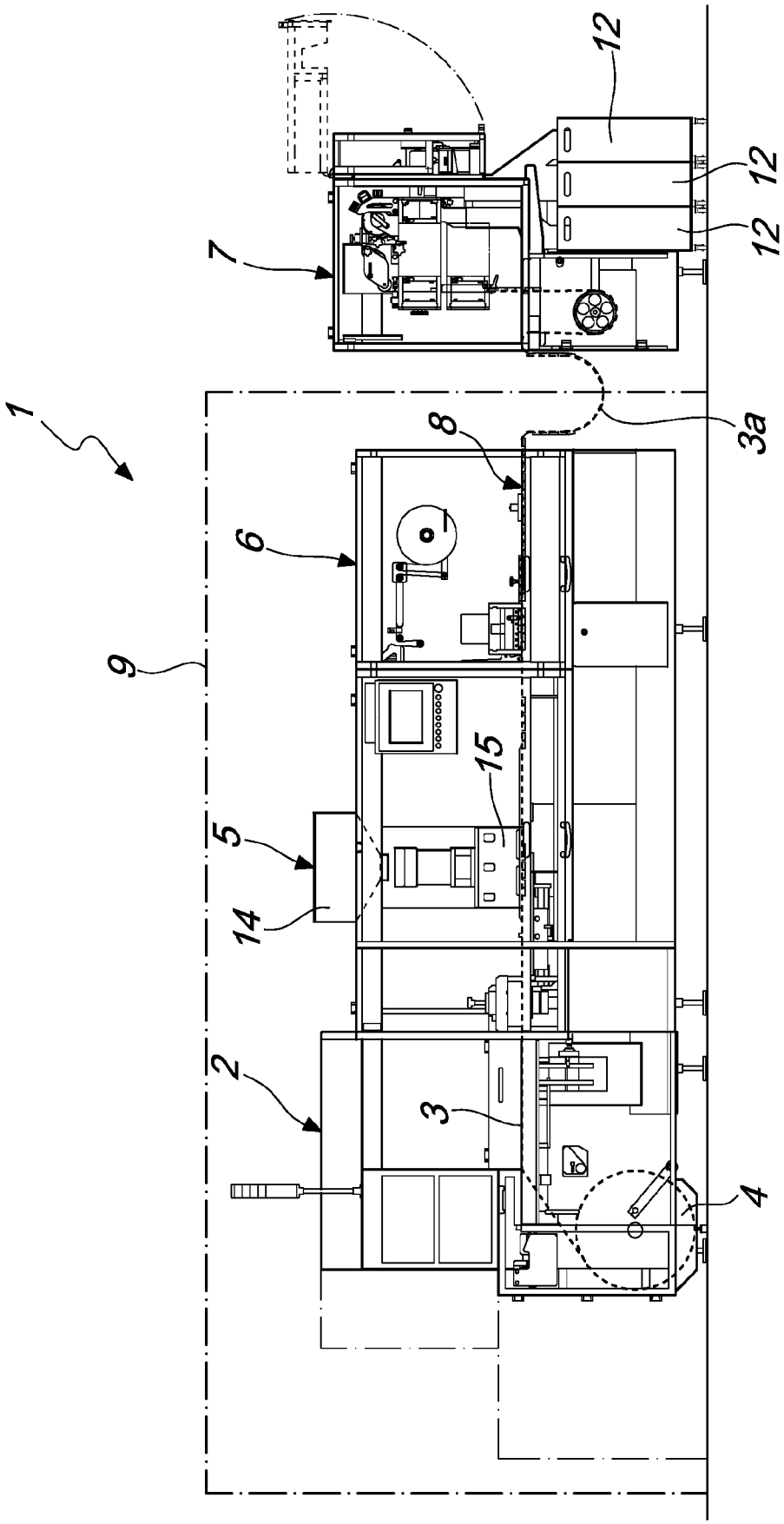

Fig. 1

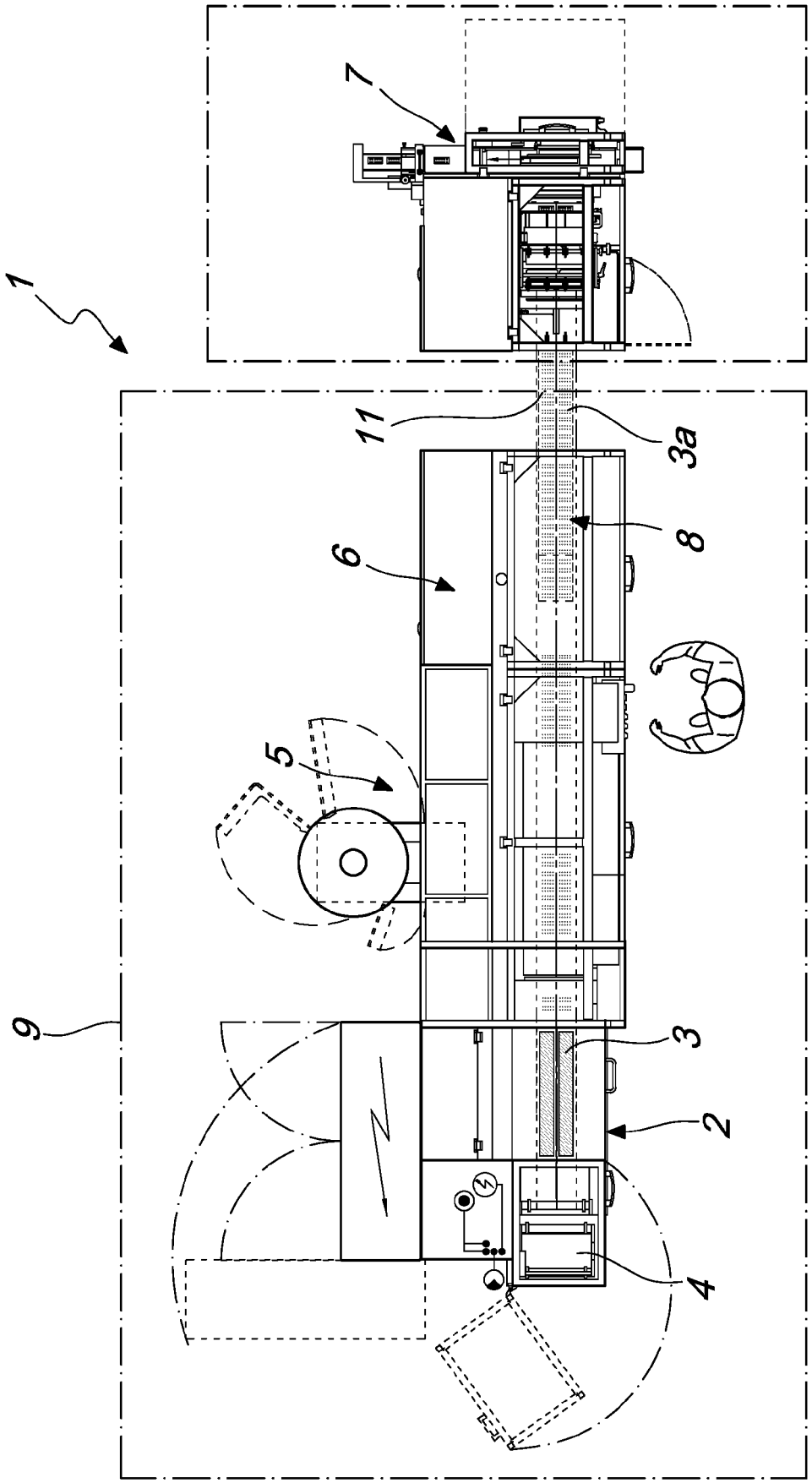

Fig. 2

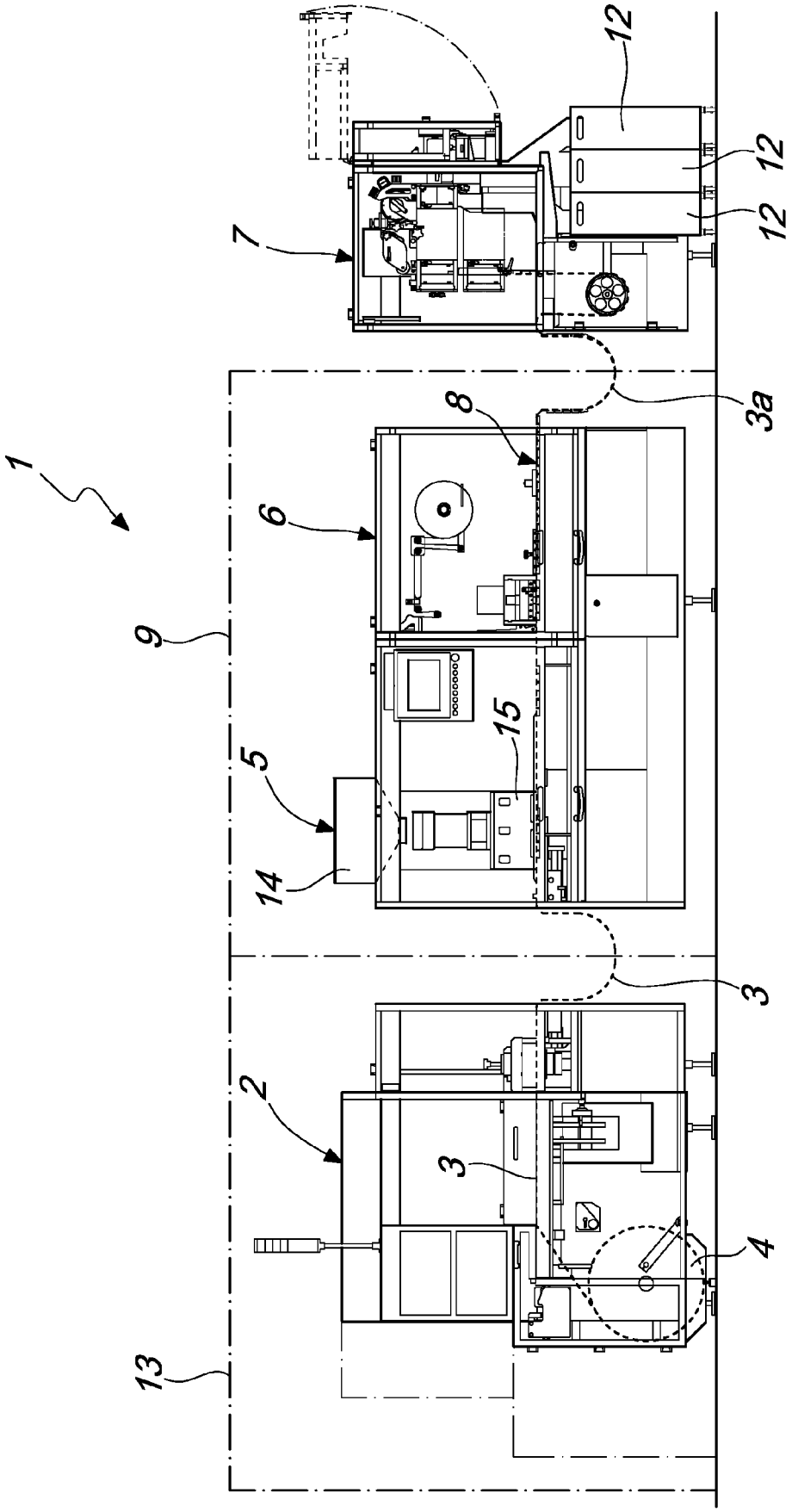

Fig. 3

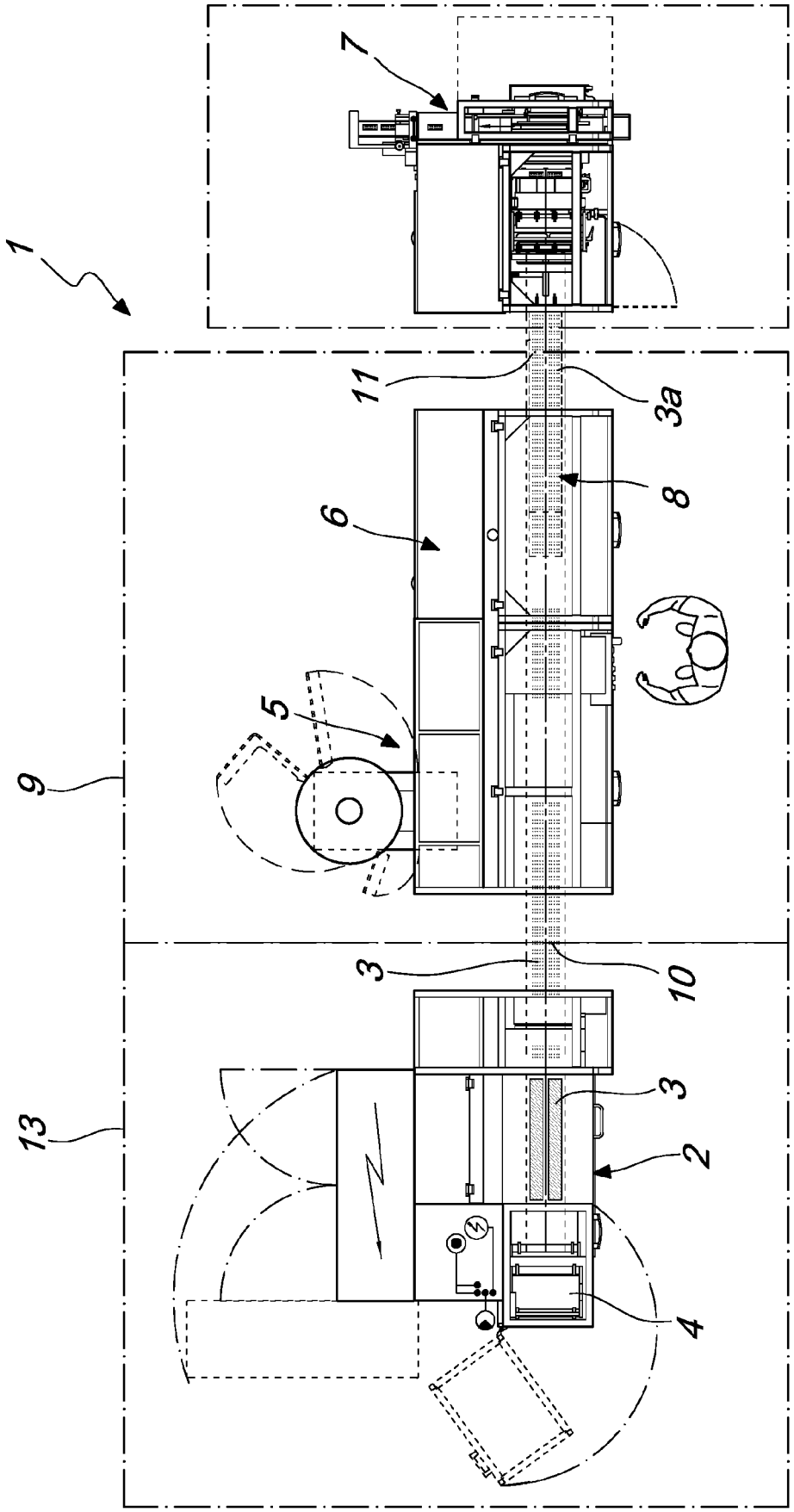

Fig. 4

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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