

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------|
| Applicant's or agent's file reference<br>17/2021PCT ME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>FOR FURTHER ACTION</b>                                |                                                                                  | See Form PCT/IPEA/416 |
| International application No.<br>PCT/IB2021/051932                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | International filing date (day/month/year)<br>09.03.2021 | Priority date (day/month/year)                                                   |                       |
| International Patent Classification (IPC) or national classification and IPC<br>INV. A61B10/02                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                          |                                                                                  |                       |
| Applicant<br>Chaffringeon, Bernard-Marie                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                          |                                                                                  |                       |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>9</u> sheets, as follows:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2).</li> <li><input type="checkbox"/> superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)).</li> </ul> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing, in the form of an Annex C/ST.25 text file, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3ter of Annex C of the Administrative Instructions).</p> |                                                          |                                                                                  |                       |
| <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                          |                                                                                  |                       |
| Date of submission of the demand<br><br>07.10.2022                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                          | Date of completion of this report<br><br>07.07.2023                              |                       |
| Name and mailing address of the international preliminary examining authority:<br> European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0<br>Fax: +49 89 2399 - 4465                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                          | Authorized officer<br><br>Hochrein, Marion<br><br>Telephone No. +49 89 2399-5720 |                       |



# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/IB2021/051932

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## Box No. I Basis of the report

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1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3(a) and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4(a))
    - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a) and (b))
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

### Description, Pages

1-20 as originally filed

### Claims, Numbers

1-19 filed with the letter of

06-10-2022

### Drawings, Sheets

1/4-4/4 as originally filed

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
5. ☐ This report has been established:
- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
  - ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91(Rules 66.4bis and 70.2(e)).

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/IB2021/051932

6. ☒ With regard to top-up searches (Rules 66.1 *ter* and 70.2(f)):
- ☒ A top-up search was carried out by this Authority on 28.11.2022 (all discovered documents are listed in the Supplemental Box Relating to Top-up Search).
  - ☐ Additional relevant documents have been discovered during the top-up search.
  - ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.
7. ☐ Supplementary international search report(s) from Authority(ies) has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

\* If item 4 applies, some or all of those sheets may be marked "superseded".

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

|                               |             |             |
|-------------------------------|-------------|-------------|
| Novelty (N)                   | Yes: Claims | <u>1-19</u> |
|                               | No: Claims  |             |
| Inventive step (IS)           | Yes: Claims | <u>1-19</u> |
|                               | No: Claims  |             |
| Industrial applicability (IA) | Yes: Claims | <u>1-19</u> |
|                               | No: Claims  |             |

2. Citations and explanations (Rule 70.7):

see separate sheet

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

see separate sheet

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1 Reference is made to the following documents:
  - D1 US 5 688 260 A (BLANTON CATHERINE CARROLL [US]) 18 November 1997 (1997-11-18)
  - D2 US 2020/390425 A1 (CHAFFRINGEON BERNARD [AE]) 17 December 2020 (2020-12-17)
  - D3 US 2 487 200 A (TRAGER MARGARET W) 8 November 1949 (1949-11-08)
  - D4 DE 20 2009 016553 U1 (MERETE MEDICAL GMBH [DE]) 15 April 2010 (2010-04-15)
  - D5 US 2018/353737 A1 (CHAFFRINGEON BERNARD [AE]) 13 December 2018 (2018-12-13)
  - D6 US 2016/120708 A1 (CHAFFRINGEON BERNARD [CH]) 5 May 2016 (2016-05-05)
- 2 D1 is regarded as being the prior art closest to the subject-matter of claim 1, and shows:

Collecting device (fig. 6&8) for sampling at least one specimen from bodily cavities of humans and animals, the collecting device having a proximal end (upper part in fig. 6 & fig. 8), which is the end of the device to first contact said bodily cavity during use and a distal end (lower part of fig. 6 & fig. 8) opposed to said proximal end,

the collecting device comprising:

  - an elongated flattened pouch (80, 82) having: an open end (62), a short side (64) opposed to the open end, situated at the proximal end of the collecting device, and two long sides (left and right of fig. 6 and fig. 8);

wherein the collecting device further comprises

  - a creasing means (84, 88, 90), having a fixed end (84), which is fixed inside the pouch at or in the vicinity of said short side and a free end (88, 90),
- 3 The subject-matter of claim 1 therefore differs from this known collecting device in that there are *two* creasing means, each having a fixed end, and in that the free end protrudes freely through said open end, and in that the collecting

device is configured such that upon pulling the free ends of the two creasing means in opposite directions each substantially perpendicular to one of the two long sides, the short side of the pouch is brought closer to the open end while the pouch adopts a creased shape.

The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

- 4 The problem to be solved by the present invention may therefore be regarded as how to provide an improved collecting device which can be easily housed in a smaller recipient while avoiding the risk of contamination by touching the pouch.

- 5 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The removal string of D1 is tied to a knot and therefore the two parts extending to the outside of the open end cannot be pulled apart to crease the collecting device of D1. The creasing in D1 is produced by pulling the removal string while holding the device, therefore potentially contaminating the collecting device, contrary to what the technical problem strives to solve. As the collecting device of D1 is a catamenial device, the contamination is not a problem, and therefore the skilled person would not be prompted to look for ways of creasing without contamination. Furthermore, none of the prior art documents D2 -D5 teaches the solution of claim 1, namely that the free ends can be pulled apart to crease the collecting device.

- 6 The subject-matter of independent method claims 16 is also novel and inventive, see the reasoning for claim 1 whose features form part of claims 16 and 17.
- 7 The subject-matter of claim 19 is also novel and inventive, see the reasoning for claim 1 whose features form part of claim 19.
- 8 Claims 2-15 are dependent on claim 1 and claims 17, 18 are dependent on claim 16 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

## **Re Item VII**

### **Certain defects in the international application**

- 9 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1-D6 is not mentioned in the description, nor are these documents identified therein.



To:

European Patent Office acting as  
International Preliminary Examination Authority  
D-80298 Munich  
Germany

06 October 2022

Our ref: 17/2021 PCT ME

Re: International Patent Application no. PCT/IB2021/051932  
in the name of: CHAFFRINGEON, Bernard-Marie

Dear Colleagues,

In response to the Written Opinion of the International Search Authority, we hereby submit the following amendments and arguments in agreement with Art. 34 PCT.

### 1. Amendments

In order to overcome the reasoned statement with regard to clarity, novelty and inventive step raised by the Examiner in WO of ISA, we hereby submit an amended set of claims 1 to 19 which is to replace the set currently on file. The amended claims are submitted as clean copy and with track changes.

#### 1.1. Claim 1 – was amended as follows:

- # The wording "*the collecting device*" has been introduced in claim 1 lines 3 and 5, as per the examiner's observation (26) of the ISR, to solve the detected lack of clarity.
- # The wording "*characterized in that the collecting device further comprises*" was introduced, as per the examiner's observation (21) of the ISR, to delimitate the features described in D1 from the technical features of the present invention.

1.2. Claim 3 was amended as follows:

the wording "*said further segment (60, 61)*" has been introduced in claim 3 lines 3 and 4, as per the examiner's observation (27) of the ISR, to solve the detected lack of clarity.

1.3 Claim 8 – has been redrafted to become dependent on claim 7. The basis for this amendment can be found in the description, paragraph [0042].

1.4. Claim 15 has been deleted.

1.5. New claim 15 is based on the original claim 17, placed above original claim 16, as per examiner observation (24) of the ISR.

1.6. Original claims 18 – 20 were renumbered into claims 17-19.

## 2. Clarity

We consider that the amended claims are now clear and overcome all the Examiner objections.

## 3. Novelty

### Novelty amended claim 1

Document D1 discloses a reusable catamenial device made of a single piece of cotton cloth folded and stitched to provide two parallel, side-by-side, elongated, multilayered cloth tubes, wherein a withdrawal string is looped through the tubes such that its ends protrude outside the tubes and are secured together, as by a knot, to hold the string in place (see column 1, Summary of the invention, first paragraph, and column 3, paragraph 5).

The collecting device of amended Claim 1 of the present invention differs from the catamenial device disclosed in D1 by the following features:

**- two creasing means (32,34), each having a fixed end (301), which is fixed inside the pouch (20) at or in the vicinity of said short side (201) and a free end (303), which protrudes freely through said open end (200) –**

D1 does not disclose a device provided with two creasing means fixed at the short side of a pouch. Instead, D1 discloses a string 84 that makes a loop through the tubes of the device, without being fixed to the device at any point. On the contrary, D1 discloses that the ends of the string have to be secured together in a knot in order to maintain the string in place so it can be used for withdrawing the tampon (see column 3, paragraph 5: "*A thin withdrawal string or cord 84 is then passed up through one tube, such as tube 80, from the bottom edge 64 to the top edge 62 of the blank, is passed over the top end 86 of the*

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*longitudinal seam formed by stitching 78, and is passed downwardly through adjoining tube 82. Ends 88 and 90 of the string 80 are secured together, as by a knot, to hold the string in place within the tampon").*

- the collecting device (1) is configured such that upon pulling the free ends (303) of the two creasing means (32, 34) in opposite directions each substantially perpendicular to one of the two long sides (202, 204), the short side (201) of the pouch (20) is brought closer to the open end (200) while the pouch (20) adopts a creased shape (22).

D1 does not disclose a collecting device configured such that the ends of two creasing means can be pulled perpendicularly to its longitudinal axis. As mentioned above, document D1 discloses that ends 88 and 90 of the string 80 do not each protrude freely, but *"are secured together, such as by a knot, to hold the string in place within the tampon"*. As such, they cannot be pulled in opposite directions perpendicular to the long sides in order to crease the device. Instead, as mentioned in column 4, the device *"[...] if it is to be collapsed, the tampon 72 is simply compressed in a lengthwise direction along axis 40, as by pulling the string 84"*.

Therefore, amended claim 1 is novel with respect to D1.

#### 4. Inventive step

##### Inventive step amended claim 1

Considering document D1 as the closest prior art, Claim 1 differs from D1 by the following features:

- two creasing means (32,34), each having a fixed end (301), which is fixed inside the pouch (20) at or in the vicinity of said short side (201), and a free end (303), which protrudes freely through said open end (200),

and

- wherein the collecting device (1) is configured such that upon pulling the free ends (303) of the two creasing means (32,34) in opposite directions each substantially perpendicular to one of the two long sides (202,204), the short side (201) of the pouch (20) is brought closer to the open end (200) while the pouch (20) adopts a creased shape (22).

As mentioned in the description, paragraphs [0027] and [0028], the effect of these technical features is that, when the creasing means are pulled, *"the entire pouch adopts a creased shape, that has significantly smaller dimensions than its extended shape"*. This has *"the advantage that the collecting device can be housed in a smaller recipient for transporting to a testing facility. Moreover, the pouch in creased shape has significantly greater rigidity than in extended shape. This makes it easier to manipulate and to introduce into a recipient, further allowing for a smaller recipient to be used, which uses less raw material and is less expensive to produce. Also, "The user can for example easily introduce the collecting device pouch-first, holding the device by the distal ends of the creasing means, thus avoiding the risk of contamination by touching the pouch."*

In view of the above, **the objective technical problem** considering D1 is to provide an improved collecting device which can be easily housed in a smaller recipient while avoiding the risk of contamination by touching the pouch.

**D1** is concerned with providing a reusable catamenial device made by folding a cloth and sewing it to produce two side-by-side tubes. A thin withdrawal string or cord is then passed up through one tube and down the other, and its ends are secured together, as by a knot, to hold the string in place. This catamenial device (column 3, last paragraph, column 4, first paragraph), is meant to be placed into the vagina by the fingers of the user after it is creased either by folding or rolling over the fingers or after it is collapsed by pulling on the string with one hand in a longitudinal direction while maintaining the cloth in place with the other hand, thus producing accordion-type folds. In order to hold the string in place within the tampon 9 so it can fulfil its role of withdrawing the tampon from the vagina, the two ends of the string must be secured together, such as by a knot (column 3, paragraph 5). Consequently, the ends of the string cannot be pulled in opposite directions in order to crease the cloth, and thus the indications that the cloth of D1 is to be creased by holding it with the fingers while pulling the string longitudinally. So, the creasing in D1 implies contaminating the cloth by touching it with the fingers, contrary to the technical problem. Thus, the skilled person, when trying to solve the problem of providing a collecting device which can be easily housed in a smaller recipient while avoiding the risk of contamination by touching the pouch, would have no reason to use the catamenial device described in D1, since it cannot be brought to smaller dimensions without touching the pouch.

Consequently, claim 1 involves an inventive step over Document D1.

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When considering the other documents, **D2** does not attempt to solve the problem of providing a collecting device that can be easily housed in a smaller recipient while avoiding the risk of contamination by touching the pouch. On the contrary, D2 teaches away from the solution provided by the present invention, mentioning that (paragraph [0057]) "The recipient of the self-sampling kit (...) has the dimensions adapted to house the entire sampling cloth. (...). At least one of the openings of said recipient has dimensions sufficient to allow the user of the kit to easily place the sampling cloth inside the recipient, *preferably without squeezing the cloth*, which might result in removing part of the collecting specimens."

Consequently, the specialist seeking an improved collecting device which can be easily housed in a smaller recipient while avoiding the risk of contamination by touching the pouch would have no reason to try to solve the technical problem by providing the sampling cloth of D2 with creasing means, since D2 explicitly teaches away from creasing the cloth.

Therefore, the skilled person would have no reason to use the device of D2 or to combine D2 and D1, and could not solve the technical problem in the same way as the present invention by combining D2 and D1, so claim 1 involves an inventive step over D2 and the combination of D2 and D1.

## 5. Summary

It is submitted that this response overcomes the objections raised by the WO of ISA. We therefore kindly request favourable reconsideration of the present application with the present redrafted set of claims.

## 6. Annexes

Amended claims 1-19, clean and with track changes

Sincerely yours,

Miruna Enescu

European Patent Attorney

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## Amended Claims

1. Collecting device (1) for sampling at least one specimen from bodily cavities of humans and animals,

the collecting device having a proximal end (101), which is the end of the device to first contact said bodily cavity during use and a distal end (103) opposed to said proximal end

comprising:

- an elongated flattened pouch (20) having:

an open end (200)

a short side (201) opposed to the open end (200), situated at the proximal end (101) of the collecting device (1), and

two long sides (202,204);

characterized in that the collecting device further comprises

- two creasing means (32,34), each having a fixed end (301), which is fixed inside the pouch (20) at or in the vicinity of said short side (201) and a free end (303), which protrudes freely through said open end (200),

wherein the collecting device (1) is configured such that upon pulling the free ends (303) of the two creasing means (32,34) in opposite directions each substantially perpendicular to one of the two long sides (202,204), the short side (201) of the pouch (20) is brought closer to the open end (200) while the pouch (20) adopts a creased shape (22).

2. Collecting device (1) according to claim 1 wherein the pouch (20) is made of a flexible fabric suitable for collecting at least one specimen such as a cell, cell residue, DNA, RNA, protein, virus, bacterium, parasite, or fungus, such as a fabric with an absorbency of 3.5 g/g or less.

3. Collecting device (1) according to claim 2, wherein the device (1) further comprises at least one further segment (60, 61) integrally formed with the fabric of the pouch (20), said further segment (60, 61) extending from the open end (200) of the pouch (20) towards the distal end (103) of the collecting device (1), and said further segment (60, 61) having dimensions such that, after the collecting device (1) is inserted into the bodily cavity, said at least one further segment (60,61) protrudes outside said bodily cavity.

4. Collecting device (1) according to claims 1-3, wherein each of said creasing means (32,34) is in the form of a thread, elastic thread, string, strip or ribbon.

5. Collecting device (1) according to claims 1-4, wherein the collecting device (1) comprises two sheets of fabric (40,41), each having a proximal margin (401) situated at the proximal end (101) of the device (1), a distal margin (403) situated at the distal end (102) of the device (1), and two lateral margins (402,404), wherein the sheets (40,41) are fastened to each other by fastening elements (25) such as continuous welding lines, spot welding rows, sewing lines, and/or glue lines to form the short side (201) and the two long sides (202,204) of the pouch (20).

6. Collecting device (1) according to claim 5, wherein said two long sides (202,204) of the pouch (20) are parallel to each other and perpendicular to said short side (201).

7. Collecting device (1) according to claims 5-6, wherein said short side (201) of the pouch (20) is situated at a distance of about 1mm to 10mm, such as 1mm to 10mm, such as 1 to 3mm, 1 to 5mm, 1 to 8mm from the proximal margin (401) of said sheets (40,41).

8. Collecting device (1) according to claim 7 wherein said short side (201) of the pouch (20) forms two proximal flaps (44,46) fixed to each other at one end by the fastening elements (25) at the short side (201) and having the opposite end free.

9. Collecting device (1) according to claims 5-8, wherein said long sides (202,204) of the pouch (20) are situated at or in the vicinity of the lateral margins (402, 404) of the sheets (40,41).

10. Collecting device (1) according to claims 5-9, wherein the fastening elements (25) at the short side (201) of the pouch (20) are made of two or more rows of welding spots (7) and/or lines of continuous welding.

11. Collecting device (1) according to claims 5-10, wherein each sheet of fabric (40,41) has a segment (50,51) that is fastened to the other sheet (41,40) to form the pouch (20) and at least one of said sheets of fabric (40, 41) has further segment (60,61), at the distal margin (403), that is not fastened.

12. Collecting device (1) according to claim 11, wherein at least one of said further segments (60,61) has a V-shape that narrows toward the distal end (103) of the collecting device (1).

13. Collecting device (1) according to claims 11-12, wherein the free end (303) of each of said creasing means (32,34) can reach out of the pouch (20) to a point that is at least 10mm beyond said open end (200) of the pouch (20), but not beyond a distal termination (603) of the further segments (60,61).

14. Collecting device (1) according to claims 5-13, wherein said fastening elements (25) forming the two long sides (202, 204) of the pouch (20) are single straight rows of welding spots (7) having substantially elongated shapes each defining a long axis (70), a proximal end (71) and a distal end (73), oriented so that said long axis (70) of each welding spot (7) forms an angle (700) to the corresponding long side (202,204) that it is part of, such that the proximal end (71) that is closer to the short side (201) of the pouch

(20) is also the end of the spot (7) that is closer to a longitudinal central axis (210) of the pouch (20), thus the long axis (70) forming an acute angle to the direction toward the proximal end (101) of the corresponding long side (202,204).

**15.** Sampling kit, comprising a collecting device (1) according to any of the preceding claims, an applicator (8) for inserting into the pouch (20) to introduce at least part of said collecting device (1) inside a bodily cavity, and a sealable recipient (9) for receiving the device (1) after sampling.

**16.** Use of a collecting device (1) according to any preceding claim for sampling of at least one specimen from bodily cavities of humans or animals such as vaginal cavity, rectal cavity, or cavity or nasal cavity.

**17.** Method for sampling at least one specimen from bodily cavities of humans or animals comprising the steps:

- a) inserting at least part of the collecting device (1) according to any of claims 1 to 14 into a bodily cavity of a human or animal,
- b) removing the collecting device (1) from the bodily cavity,
- c) pulling said two creasing means (32,34) by their distal extremities (303), at the same time, in opposite directions, away from each other and substantially perpendicular to the long sides (202,204) of the pouch (20), thereby creasing the pouch into a creased shape (22) ,
- d) placing the collecting device (1) with the pouch (20) in creased shape (22) inside a sealable recipient (9)
- e) sealing the recipient (9),
- f) sending the sealed recipient (9) to a testing facility, such as a laboratory, for testing and/or diagnostic.

**18.** Method for sampling according to claim 17, wherein after step a) and before step b), the pouch (20) is left inserted into the bodily cavity for a period of time of at least 2 minutes, preferably for 2 to 30 minutes, such as 2 to 15 minutes.

**19.** A process for manufacturing a collecting device (1) according to claims 5-14, the process comprising:

- a) continuously feeding to a fastening and cutting machine, from separate coils, two similar sheets of fabric (40,41) and two creasing means (32,34), for example two threads, such that they assemble on a manufacturing line in a sandwich-like assembly with the two sheets of fabric (40,41) covering each other and the two creasing means (32,34) running along between said two sheets of fabric (40, 41);

- b) applying fastening means to said sandwich-like assembly, for example welding means, such as ultrasound welding, thus fastening said two sheets of fabric (40,41) together by fastening elements (25) such as rows of welding spots and/or lines of continuous welding to form the pouch (20) of the collecting device (1) while at the same time the fastening elements (25) forming the short side (201) of the pouch (20) also fix the two creasing means (32,34) inside the pouch (20), and simultaneously
- c) applying cutting means to cut at the same time the two sheets of fabric (40,42) and the two creasing means (32,34) to obtain the desired final shape of the collecting device.