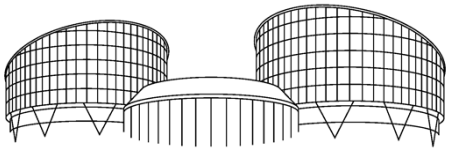

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

FIFTH SECTION

CASE OF S.O. v. SPAIN

(Application no. 5742/22)

JUDGMENT

Art 8 • Positive obligations • Private life • Applicant's claim concerning the absence of valid informed consent concerning the expansion of the scope of her breast-conserving surgery • Absence of any deficiencies in respect of the applicable domestic regulatory framework • Applicant's allegations before the domestic courts of significant importance in establishing the scope of the duty incumbent on the medical professionals involved in her care to seek her informed consent • Inadequate response to the applicant's complaint • Domestic courts' failure to consider important dimensions of women's sexuality • Practical implementation of the existing framework deficient and not affording sufficient respect for the applicant's autonomy

Prepared by the Registry. Does not bind the Court.

STRASBOURG

26 June 2025

This judgment will become final in the circumstances set out in Article 44 § 2 of the Convention. It may be subject to editorial revision.

In the case of S.O. v. Spain,

The European Court of Human Rights (Fifth Section), sitting as a Chamber composed of:

Kateřina Šimáčková*, President*,
María Elósegui,
Gilberto Felici,
Andreas Zünd,
Diana Sârcu,
Mykola Gnatovskyy,
Vahe Grigoryan*, judges*,

and Martina Keller, *Deputy Section Registrar,*

Having regard to:

the application (no. 5742/22) against the Kingdom of Spain lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") by a Venezuelan national, Ms S.O. ("the applicant"), on 21 January 2022;

the decision to give notice to the Spanish Government ("the Government") of the complaints concerning Article 8 and to declare the remainder of the application inadmissible;

the decision not to have the applicant's name disclosed;

the parties' observations;

the decision to uphold the Government's objection to the examination of the application by a Committee;

Having deliberated in private on 3 June 2025,

Delivers the following judgment, which was adopted on that date:

INTRODUCTION

1. The case concerns, under Article 8 of the Convention, the alleged absence of informed consent by the applicant to the resection of her nipple-areola complex during breast-conserving surgery.

THE FACTS

2. The applicant was born in 1956 and lives in Madrid. She was represented by Ms E. Rodilla Alvarez, a lawyer practising in Madrid.

3. The Government were represented by their co-Agent, Ms H. E. Nicolás Martínez.

4. The facts of the case may be summarised as follows.

5. In June 2016 the applicant was diagnosed with breast cancer affecting her right breast. She had previously been treated for breast cancer affecting her left breast in 2005. Since October 2016 she has been treated at the Gómez Ulla Hospital in Madrid (*Hospital Central de la Defensa – Gómez Ulla*, hereinafter "the hospital"). On 5 October 2016 the applicant underwent

magnetic resonance imaging, which showed a lump located above her right areola, fifteen millimetres from the nipple. In January 2017 the hospital's Tumour Committee (a multi-disciplinary team of healthcare professionals who meet regularly to discuss and plan the treatment of cancer patients) suggested that breast-conserving surgery would be the most appropriate treatment in the applicant's case.

6. On 18 January 2017 the applicant was informed of the proposed surgical intervention and was provided with an informed consent form, which she signed on 1 February 2017, agreeing to breast-conserving surgery. The document stated:

> I have been informed that breast-conserving surgery is necessary/advisable in my situation because I have breast cancer.
>
> 1. Owing to the clinical situation, the progression of the tumour, its location and its characteristics, it is possible for me to be treated by way of breast-conserving surgery, with results similar to those obtained through more aggressive surgical therapies:
>
> a) Removal of the [damaged] area of the breast, previously marked with Kopans needles ...
>
> b) Lumpectomy.
>
> c) Segmental resection (resection of a segment of breast tissue and the underlying pectoralis fascia - in case of malignancy).
>
> d) Quadrantectomy or partial mastectomy (removal of one quadrant of the entire breast and the underlying pectoralis fascia - in case of malignancy).
>
> e) Subcutaneous mastectomy (removal of the mammary gland, leaving the skin, subcutaneous fat tissue and the nipple).
>
> f) Simple mastectomy (complete removal of the mammary gland, including the skin, subcutaneous fat tissue and the nipple).
>
> g) Axillary lymphadenectomy (removal of axillary lymph nodes), as a complementary treatment to breast surgery for malignancy.
>
> I have been informed that complementary treatment with radiotherapy on the remaining breast – in case of malignancy – is generally necessary, to which I have agreed. In that case, other treatment may also be necessary (chemotherapy, hormonotherapy, rehabilitation, etc).
>
> In my case, in principle, a quadrantectomy and a right axillary lymphadenectomy will be performed.
>
> 2. Complications and/or risks and failures: every surgical intervention, on account both of the surgical technique and the patient's state of health ... implicitly involves a number of common and potentially serious complications that may require complementary treatment, both medical and surgical, and carries a minimal risk of a fatal outcome.
>
> ...
>
> If something unforeseen occurs during the surgical intervention, the medical team may modify the usual or planned surgical technique.

> 3. Owing to my current situation, the doctor has explained that risks or complications such as ... [blank] may arise.
>
> ...
>
> 6. Pathological Anatomy: The sample of tissue removed during the surgery will be subject to an anatomopathological examination after and/or during the surgery (*intraoperatorio*) to obtain a final diagnosis, and the patient and/or her relatives or legal representative will be informed of the results of that examination.
>
> I understand the explanations that I have been given in clear and simple language; the doctor has allowed me to make comments and has clarified all the doubts I have raised.
>
> I also understand that, at any moment and without the need for any explanation, I can revoke this consent.
>
> I therefore declare that I am satisfied with the information I have received and that I understand the scope and the risks of the proposed surgical treatment.
>
> In these circumstances, I consent to undergo breast-conserving surgery.

7. The medical file contains an entry of 1 February 2017 which states "[d]oubts have been solved. She understands and consents to the intervention". The content of the information verbally given at that moment, of the doubts raised by the applicant and/or of the answers given by the medical team in reply to those concerns are not recorded in the medical file, as submitted to the Court.

8. On 2 February 2017 the applicant underwent surgery. During the operation, the nipple-areola complex ("the NAC") was resected. According to the available medical reports, during the operation two samples of breast tissue were sent to the Pathological Anatomy Unit for immediate analysis. On receipt of the analysis results, the resection area was extended with its lower margins going beyond the NAC, which was also removed.

9. On 13 June 2017 the applicant lodged a complaint with the Directorate General of Patient Care of the Madrid Autonomous Community. She argued that she had not been informed of the possibility of a resection of the nipple and areola, that she had consented only to breast-conserving surgery and that the cancer had not spread to the nipple and areola.

10. In response, the Directorate sent the applicant a report prepared by the Head of the hospital's Gynaecology Department on 21 June 2017. The report, based on information contained in the applicant's medical file, stated the following:

> A lumpectomy was performed, for which consent had been given in the form, and the sample was sent to the Pathological Anatomy Unit to determine the [cancer-] free margins. The Unit confirmed that cancer cells had spread to the edge adjacent to the NAC, so [the medical team] extended the resection margins, which resulted in the removal of the NAC [as a precautionary measure] for the patient's safety. In oncological surgery, the priority is total removal of the tumour, with ... a clearance ... to ensure the success of the intervention, aesthetic [considerations] which can be resolved with subsequent surgery, being secondary.

> With regard to oncological procedures, the informed consent form states: should something unforeseen occur during the surgical intervention, the medical team may modify the usual or planned surgical technique.
>
> It is evident that margins affected by a tumour cannot be left *in situ* during surgery, as otherwise the operation would not achieve the expected result. This is an unforeseen situation which requires the surgeon to extend the surgical technique, without modifying it. The surgery was breast-conserving, given that no mastectomy was required; the breast was conserved, but was tumour-free ...
>
> When conservative surgery is performed in the case of breast cancer, the relevant protocols require a clearance around the tumour. Although, in the applicant's case, the areola was not affected, it was [however] within that surgical margin, and thus had to be removed. This was done to avoid the possibility of cancer cells remaining near the edge generating a new tumour, resulting in the failure of the conservative surgery and a significant risk to the patient. The NAC can be reconstructed through subsequent surgery ... so that its absence does not entail permanent aesthetic loss, but, as in this case, [its removal] improves the patient's [prognosis].

11. On 13 September 2017 the applicant lodged a complaint with the Health Department of the Madrid Autonomous Community, alleging the State's liability. She argued that although the cancer had not invaded her nipple and areola, those parts of her breast had been resected, and that she had given informed consent only to breast-conserving surgery and the removal of lymph nodes. She claimed 100,000 euros (EUR) in compensation for injury and damage.

12. As part of those proceedings, on 3 November 2017 the Head of the Gynaecology Department prepared a second report, essentially reiterating the content of his report of 21 June 2017 (see paragraph 10 above), with some clarifications:

> A quadrantectomy with axillary lymphadenectomy was performed.... From an oncological point of view, for surgery to be safe and effective and to minimise the risk of subsequent relapse, the relevant protocol of the Spanish Society of Obstetrics and Gynaecology requires a [cancer-free] clearance not less than a specific number of millimetres. As that was not the [applicant's] case, we proceeded to extend the resection, resulting in the removal of the NAC.
>
> In oncological surgery, the patient's safety and future health is prioritised over aesthetic [considerations], which may be resolved through subsequent surgery or medical tattoos. Furthermore, given that it concerns an oncological procedure in which the borders of the [tumour] are not known until [the surgery], the following paragraph is included in the informed consent form: "if, during the surgical intervention, something unforeseen occurs, the medical team may modify the usual or planned surgical technique".
>
> In [the applicant's case], the technique was not modified, but rather extended while continuing with conserving surgery (that is, preserving the breast), which was the essence of the informed consent form signed. The oncological objective was met: the breast was preserved, free from tumour.
>
> ...
>
> I consider that the medical intervention undertaken was appropriate in the patient's case, considering that it was her second breast cancer, and [doctors] must be extremely

> careful to avoid a recurrence as a consequence of poorly executed oncological surgery. The [applicant] has an elevated risk of [recurrence], and that must be avoided as far as possible.

13. On 15 December 2017 the Head of the hospital's Pathological Anatomy Unit submitted a report explaining that the pathology report issued by the unit in the course of the operation, a few minutes after receipt of the samples, had indicated that there was a close clearance of two millimetres between the tumour and the edge of the sample, but that the tumour bordered on the nipple-areola area. That same evening, the unit had received three additional samples, including a sample from the nipple and areola; analysis of that sample showed that the nipple and areola had not been invaded by the tumour. The hospital report concluded that while the tumour's invasion into the surgical margins, or the proximity of those margins to the nipple-areola area, did not necessarily imply that that area had also been invaded, the relevant protocols required a clearance, for oncological safety.

14. On 12 February 2018 the Health Inspectorate issued a report on the applicant's complaint, concluding that:

> 1. The case had been studied by the hospital's Tumour Committee, which concluded that surgery should be performed.
>
> 2. The recommendation to remove the NAC in cases where [cancer cells are found] less than two millimetres away from the nipple is contained in the publications listed in the bibliography.
>
> 3.The patient's informed consent had been given in writing and had been completed orally in the course of several consultations between the patient and the medical team throughout the process; these are documented in the patient's medical records.
>
> 4.The informed consent document expressly states that the medical team could modify the technique. The patient was provided with that document fifteen days before the intervention, to ensure that she fully understood [the information contained within].
>
> 5. The removal of lymph nodes was not unwarranted ...

In particular, concerning the applicant's informed consent, it stated:

> The main objective of an informed consent form is to inform [a patient] of therapeutic alternatives, the appropriate intervention in their case, and about the risks and potential complications of that intervention.
>
> ... an informed consent form is not a rigid document, but rather one that accounts for potential scenarios that may require a modification to an intervention or treatment, in order to adapt more appropriately to the patient's pathology...
>
> The patient was informed in detail and on several occasions and during different consultations (as shown in her medical records) of the therapeutic alternatives.
>
> The written document was provided sufficiently in advance (fifteen days [before the surgical procedure]) so she could ask about any doubts she had before the intervention.

15. In the absence of a reply from the Health Department, amounting to a rejection of the claim under domestic law, on 4 September 2018 the applicant lodged a civil claim with the Madrid High Court of Justice ("the High

Court"). She argued that she had given her consent to breast-conserving surgery, but she had not been told that the removal of the NAC was a possibility, nor had she been informed about the "surgical margin" technique, which implied a risk of the removal of the NAC. She further argued that the intervention in question could have been performed without removing the areola and the nipple; since they had not been invaded by cancer cells, they could have been conserved.

She argued that there was a clear causal link between the injuries she had sustained and the shortcomings on the part of the hospital, and that there were several elements to the alleged damage: (i) her right as a patient to choose the best treatment and the absence of adequate information in that regard; (ii) the psychological damage arising from the discovery that she had lost her nipple and areola; (iii) the actual loss of the nipple and areola, which could have been avoided using a different surgical technique.

The applicant concluded that the pre-operation information should have included the possibility that a resection of the nipple and areola might be performed, as, given the location and the "surgical margin" technique, such a scenario had not been unforeseeable. She added that the margin of two millimetres was not universally accepted, as other hospitals used a more reduced margin (one millimetre or less). Lastly, she stated that her areola and nipple should have been preserved until receipt of the biopsy results confirming that they had not been invaded by the tumour (see paragraph 13 above), even if that implied the possibility of a second operation. Such an operation could have been performed in a different way had she been given an opportunity to express her opinion.

16. In addition to the report from the Health Inspectorate (see paragraph 14 above), several other reports commissioned by the applicant and a co-defendant insurance company were filed with the High Court.

17. The Spanish Association Against Cancer (*Asociación Española Contra el Cáncer*) filed a report stating that it had provided social and psychological care to the applicant, and that she had participated in their physical exercise programmes. According to its files, the applicant had reported psychological suffering as a result of the intervention. Specifically, she referred to problems with body image and rejection from her partner in their sexual life. The scars, the lack of areola and nipple and the asymmetric location in respect of her other breast had had a severe emotional impact on her. The Association also stated that, based on its understanding as a specialised entity, breast cancer surgery was a traumatic experience for women and various studies showed that women faced psychological issues and a deterioration in their quality of life in relation to breast cancer and its treatments. Approximately 30% of women undergoing breast cancer treatment suffered psychological issues, including feelings of mutilation and alteration of their body image, lowered self-esteem, loss of the feeling of femininity, and diminishment of sexual desire and function.

18. On a request by the applicant, a court-appointed forensic doctor submitted an expert report. The report concluded that the medical intervention had been appropriate. The removal of the areola and the nipple had been a consequence of the tumour's location and its proximity to the NAC, and that had the areola not been removed, the cancer would not have been resected with a sufficient surgical margin. The removal of the lymph nodes had also been appropriate.

19. On a request by the co-defendant, a specialist in gynaecology and obstetrics submitted an expert report which concluded that the care provided to the applicant had been in accordance with the oncological practical guides and with the *lex artis*. Concerning the applicant's informed consent, the expert noted that the informed consent form had specified that the technique could be modified if something unforeseen occurred, and affirmed that, in the applicant's case, the unforeseen circumstances had been that the cancer cells had spread into the margin in contact with the NAC; even in those circumstances, the surgery had not in fact been modified, but merely extended.

20. In her final submissions to the High Court, the applicant reiterated her initial claims but, acknowledging that there was no evidence to support her argument that the removal of the lymph nodes had been unnecessary, reduced the amount of compensation she was seeking to EUR 50,000.

21. On 30 September 2020 the High Court dismissed the applicant's claim, finding that there had been no breach of the *lex artis*. In view of the medical and forensic reports submitted (see paragraphs 16–19 above) and the evidence from the Heads of the hospital's Gynaecology Department and Pathological Anatomy Unit, the High Court found that the primary consideration had been to ensure successful breast-conserving surgery, and that this had resulted in an extension of the area to be removed. This had been aimed at ensuring that the margins were cancer free. Furthermore, the alternative proposed by the applicant, namely suspending the surgical intervention, pending the results of the biopsy and before deciding on removal of the NAC, had not been the only valid option according to the *lex artis*.

22. With regard to informed consent, the High Court referred to the constitutional case-law on the matter, namely the Constitutional Court's judgment 37/2011, of 28 March 2011 (see, for a summary of this judgment, *Pindo Mulla v. Spain* [GC], no. 15541/20, §§ 63-65, 17 September 2024). The High Court then concluded that the informed consent form, as signed by the applicant, had been adequate and sufficient, for the following reasons: (i) it had referred to breast-conserving surgery, but in the context of a disease where "oncological safety" (*seguridad oncológica*) was the primary objective; (ii) that objective had been the reason for "extending the surgical technique"; (iii) the possibility of varying the surgical technique had been included in the information given to the applicant, since the informed consent form had stated that the planned technique could be modified in the event of

unforeseen circumstances. In that connection, the reports submitted to the court showed that the medical treatment had been appropriate. Lastly, the applicant had signed the informed consent form, indicating that she was satisfied with the information she had received and that she understood the scope and risks of the proposed surgical procedure. There had therefore been no breach of the applicant's right to informed consent.

23. The applicant lodged an appeal on points of law arguing that the High Court's assessment in relation to the informed consent had been contrary to her autonomy. She reiterated that the information contained in the informed consent form was generic, and that she had not been informed of the possibility of the removal of the NAC, despite it being a foreseeable risk. She had been deprived of her right to refuse an intervention, even if it was recommended or needed from a medical perspective. Her autonomy had therefore been replaced by the criteria of the medical team. On 11 March 2021 the Supreme Court declared the appeal inadmissible, considering that there was no objective legal interest (*interés casacional objetivo*) as required under domestic law.

24. The applicant lodged an amparo appeal, alleging a breach of her rights to effective judicial protection and to physical and moral integrity under Articles 24 and 15 of the Constitution respectively. On 15 July 2021 the Constitutional Court declared that appeal inadmissible on the ground that it had no constitutional relevance.

RELEVANT LEGAL FRAMEWORK

25. Article 15 of the Spanish Constitution states:

Article 15

"Everyone has the right to life and to physical and moral integrity ...."

26. The relevant provisions of Act No. 41/2002 of 14 November 2002 regulating patient autonomy and rights and obligations regarding clinical information and documentation read as follows:

Article 2. Basic principles

"...

2. Any act in the field of health requires, as a general rule, the prior consent of patients or users. Consent, which must be obtained after the patient receives adequate information, shall be given in writing in the cases provided for in the Act.

3. The patient or user has the right to freely decide, after receiving the appropriate information, among the available clinical options.

4. Every patient or user has the right to refuse treatment, except in the cases determined in the Act. Their refusal of treatment shall be recorded in writing.

...

6. Every professional involved in health care is required [...] to fulfil the duty of providing information and clinical documents, and to respect the decisions taken freely and voluntarily by the patient.

...”

Article 8. Informed consent

“1. Any act regarding the health of a patient requires the free and voluntary consent of the person concerned, once he or she has received the information provided for in Article 4 and has assessed the options specific to the case.

2. Consent shall as a general rule be given orally.

However, it shall be given in writing in the following cases: surgical intervention, invasive diagnostic and therapeutic procedures and, in general, the application of procedures that entail risks or inconveniences [that will have] notable and foreseeable negative repercussions on the patient’s health.

3. Written consent from the patient shall be needed for each specific act mentioned in the previous subsection, without prejudice to the possibility of incorporating annexes and other general information, and shall contain enough information regarding the procedure and its risks.

...

5. The patient may freely revoke his or her consent in writing at any time”.

Article 9. Limits to informed consent and consent by representation

“...

2. Doctors may carry out clinical interventions that are essential for the patient’s health, without the patient’s consent, in the following cases:

...

b) When there is an immediate serious risk to the physical or psychological integrity of the patient and it is not possible to obtain his or her authorisation, [but first] consulting, when circumstances permit, his or her relatives or persons with ties to him or her.

...”

Article 10. Conditions pertaining to informed written consent

“1. The doctor shall provide the patient with the following basic information before obtaining written consent [from him or her]:

(a) relevant or major consequences that the intervention is certain to give rise to;

(b) risks relating to the patient’s personal or professional circumstances;

(c) risks likely to occur under normal conditions, in line with experience and the current stage of scientific progress or directly related to the type of intervention [in question];

(d) contraindications.

2. The doctor in charge shall take into account in each case the fact that the more uncertain the outcome of an operation, the greater the need for the patient's prior written consent".

27. The Convention on Human Rights and Biomedicine (the Oviedo Convention), in force since 1 December 1999, and ratified by Spain, states with regard to informed consent:

Article 5 - General rule

"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time".

Article 8 – Emergency situation

"When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned".

The relevant sections of its Explanatory Report are set out in *Pindo Mulla v. Spain* ([GC], no. 15541/20, § 72, 17 September 2024).

THE LAW

I. ALLEGED VIOLATION OF ARTICLE 8 OF THE CONVENTION

28. The applicant complained that she had not given valid consent to the removal of her nipple-areola complex ("the NAC") during surgery, which had therefore been performed in breach of her right to private life as provided for in Article 8 of the Convention, which reads as follows:

"1. Everyone has the right to respect for his private and family life, his home and his correspondence.

2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

A. Admissibility

29. The Court notes that the application is neither manifestly ill-founded nor inadmissible on any other grounds listed in Article 35 of the Convention. It must therefore be declared admissible.

B. Merits

1. The parties' submissions

(a) The applicant

30. The applicant argued that she had not been sufficiently and clearly informed about the risks involved in the surgery and, as such, she had been unable to give her free and informed consent. In particular, while she had consented to breast-conserving surgery, she had not been duly informed that a resection of the NAC might ensue. The mention in the form of the possibility of modifying the intervention was not specific in that regard. The applicant considered that, since a resection of the NAC was not a matter of emergency or an unforeseeable possibility, the doctors should have specifically informed her of that possibility in advance, but they did not. Thus, her consent had not been based on a process of reflection which included resection of the NAC as a possibility and, consequently, did not cover that specific intervention. Furthermore, she argued that a resection of the NAC was not only a relevant potential consequence of the intervention, but one of significant importance for the well-being of any woman, and that the medical team had attached limited importance to it. She stressed in this regard that the medical reports referred to the possibility of solving the aesthetic aspect of the operation with tattoos, that one of the experts heard by the High Court considered that it was not prudent to inform about that specific risk and that she only became aware of the removal of the NAC once she was discharged from the hospital. In contrast to her submissions in the domestic proceedings, the applicant did not argue before the Court that the intervention, as ultimately performed, had been unnecessary or inadequate in her situation.

(b) The Government

31. The Government considered that, in the present case, the resection of the NAC could not be considered a medical intervention to which the applicant had not consented. They noted that (i) the applicant had been informed of the need for the intervention and about the envisaged surgical technique and had voluntarily agreed to the scheduled surgery; (ii) she had had sufficient time, namely more than two weeks, to examine the informed consent form and to raise any doubts or objections; (iii) she had signed the informed consent form, stating that she had been duly informed that the intervention would in principle be a "quadrantectomy", but accepting that the procedure could be modified should something unforeseen occur.

The Government stated that the resection of the applicant's NAC had not been envisaged when the intervention was being planned but had resulted from the analysis carried out during surgery. Since the relevant rules on informed consent emerging from national and international law (see

paragraphs 26 and 27 above) did not require a detailed explanation of all possible risks, the information given in the applicant's case had been adequate. In any event, the domestic courts had sufficiently considered all the relevant elements and circumstances. Thus, there had been no interference with the applicant's rights under Article 8.

In any case, even accepting that there had been an interference with the applicant's private life, it had not been in breach of Article 8. The Government argued that the Spanish legal framework guaranteed the right of patients to be informed of the foreseeable consequences of proposed medical interventions and, in the present case, doctors had fulfilled their obligation to provide the applicant with sufficient information about the relevant intervention and had acted on the basis of her consent.

2. The Court's assessment

(a) General principles

32. The Court reaffirms that although the right to health is not as such among the rights guaranteed under the Convention and the Protocols thereto (see *Jurica v. Croatia*, no. 30376/13, § 84, 2 May 2017, and the cases cited therein), the High Contracting Parties have, parallel to their positive obligations under Article 2 of the Convention, a positive obligation under Article 8, firstly, to have in place regulations compelling both public and private hospitals to adopt appropriate measures for the protection of their patients' physical integrity and, secondly, to provide victims of medical negligence with access to proceedings in which they may, where appropriate, obtain compensation for damage (see *Y.P. v. Russia*, no. 43399/13, § 49, 20 September 2022, and the cases cited therein).

33. A patient's right to give informed consent to medical interventions has occupied a prominent place in the Court's case-law. It has been established that States are bound to adopt the necessary regulatory measures to ensure that doctors consider the foreseeable consequences for their patients' physical integrity of a planned medical procedure, and to inform patients of these consequences beforehand, in such a way that they are able to give informed consent. As a corollary to this, if a foreseeable risk of this nature materialises without the patient having been duly informed in advance by doctors, the State Party concerned may potentially be liable under Article 8 for this lack of information (see *Trocellier v. France* (dec.), no. 75725/01, § 4, ECHR 2006-XIV; *Codarcea v. Romania*, no. 31675/04, § 105, 2 June 2009; *Csoma v. Romania*, no. 8759/05, § 42, 15 January 2013; *Reyes Jimenez v. Spain*, no. 57020/18, § 30, 8 March 2022; and *Mayboroda v. Ukraine*, no. 14709/07, § 52, 13 April 2023). A positive obligation on the State to put in place a regulatory framework must be understood in a sense which includes the duty to ensure the effective functioning of that regulatory framework. The

regulatory duties thus encompass necessary measures to ensure implementation, including supervision and enforcement (see *Mayboroda*, cited above, § 53). At the same time, as long as the State has taken the necessary measures for securing high professional standards among healthcare professionals and protecting both the physical and mental integrity of patients, matters such as an error in judgment on the part of a healthcare professional or poor coordination between such professionals in the context of a particular patient's treatment are not in themselves sufficient to hold a State accountable for a breach of the positive obligations under Article 8 (ibid., § 54).

34. The Court has also examined whether the consent procedure laid down in the law of the respondent State was correctly followed. In this respect, the Court has stated that even if the Convention does not lay down any particular form of consent, where certain requirements are imposed by domestic law, these must be fulfilled; if they are not, an adequate and effective response to the patient's complaint is required from the domestic system (see *Pindo Mulla v. Spain* [GC], no. 15541/20, § 138, 17 September 2024).

(b) Application of those principles to the present case

35. The Court notes that the medical proceedings at issue, namely the removal of the applicant's NAC in the context of a breast-conserving surgery, is a type of intervention that bears on important aspects of a woman's personal integrity, including her physical and mental well-being, her image and self-esteem, and her sexual life, which are important elements of the personal sphere protected by Article 8 (see paragraph 32 above). Consequently, Article 8 is applicable in the circumstances of the present case.

36. The scope of the applicant's complaint before the Court is limited to the failure to obtain adequate and sufficient consent in respect of the NAC resection. Although in the domestic proceedings she also argued that a different surgical approach could have been used, she has not raised this complaint in her application to the Court.

37. Therefore, the issue at stake is whether the State complied with the positive obligations under Article 8 to protect the applicant's right to give informed consent to a medical intervention, namely by putting in place a regulatory framework and ensuring its effective functioning (see paragraphs 32 and 33 above).

38. With regards to the regulatory framework, the Court has already had occasion to consider the Spanish domestic law provisions governing the giving of consent and has observed that they are fully in conformity with the corresponding provisions of the Oviedo Convention (see *Pindo Mulla,* cited above, § 154). It has noted in this connection that the provisions of Spanish law on patient autonomy and on rights and obligations concerning information, as confirmed by domestic practice, explicitly require doctors to

provide patients with sufficient and relevant information to enable them to give informed consent to a medical intervention, including sufficient information on any related risks. In addition, the national legal provisions specify that specific interventions ("surgical interventions ... and, in general, the use of procedures involving risks or presenting disadvantages with known and foreseeable negative consequences for the patient's health") require consent to be given in writing, with very narrowly defined exceptions (for example in cases where there exists an immediate and serious danger to the person's life and where the patient or his or her relatives are not be in a position to give such consent; see *Reyes Jimenez*, cited above, § 32).

39. Therefore, the Court does not discern any deficiencies in respect of the regulatory framework applicable in the respondent State that could entail a violation of the State's positive obligations under Article 8 (see, *mutatis mutandis*, *Traskunova v. Russia*, no. 21648/11, § 75, 30 August 2022). The Court would thus examine whether the practical implementation of that legal framework in the present case afforded sufficient respect for the applicant's autonomy.

40. In the present case the applicant's consent to the surgical intervention in question was sought and indeed given, albeit allegedly without any discussion as regards the possible removal of the NAC in order to achieve the aim of surgery, that is, removal of the cancer (see, *mutatis mutandis*, *Mayboroda*, cited above, § 57, and, *a contrario*, *Csoma*, cited above, and *Ioniță v. Romania*, no. 81270/12, § 84, 10 January 2017, where the applicants' consent was absent; *Traskunova v. Russia*, cited above, where the applicant had not received full information concerning her participation in a clinical trial; and *Y.P. v. Russia*, cited above, where the applicant's consent excluded the sterilisation performed).

41. The applicant had access to a remedy enabling her to seek redress for the damage suffered as a result of the medical procedure (see *Csoma*, cited above, § 53; *Reyes Jimenez*, cited above, § 33; and *Y.P. v. Russia*, cited above, § 58). Namely, she argued before the domestic courts that she had not been properly informed of the possibility of having her NAC resected during the breast-conserving surgery; in her view, resection had not been unforeseeable for the medical team and there had been no incident during surgery or an urgent situation that would have justified the failure to obtain her explicit consent for it (see paragraph 15 above).

42. The Court will thus examine whether the manner in which the applicant's complaints regarding the absence of sufficient informed consent concerning the expansion of the scope of the surgery were addressed by the domestic authorities can be regarded as securing the requisite protection and thus satisfying the State's positive obligations under Article 8 of the Convention (see, *mutatis mutandis*, *Reyes Jimenez*, cited above, § 33).

43. The High Court considered that the informed consent form signed by the applicant had been sufficient because (i) it concerned breast-conserving

surgery in which the primary objective had been to remove the cancer; (ii) that objective had been the reason for modifying the technique; and (iii) the informed consent form stated that the technique could be modified if anything unforeseen occurred. Furthermore, the applicant had acknowledged in the form that she was satisfied with the information received and that she understood the scope and risks of the proposed surgery (see paragraph 22 above).

44. It appears from the material in the case that the objective of the breast cancer surgery was to remove the cancer, if possible in its entirety, including by a surgical margin, and that an intraoperative modification of surgical technique may sometimes be necessary to achieve that goal. However, the Court reiterates that, since the applicant was a mentally competent adult patient, her informed consent was a prerequisite to the procedure, even assuming that the latter was a necessity from a medical point of view (see *Y.P. v. Russia*, cited above, § 55).

45. The Court will next assess whether, as held by the High Court, the consent given by the applicant can be considered sufficient to cover the modification of surgical technique which resulted in removal of the NAC.

46. First, the High Court considered that the informed consent form signed by the applicant had been sufficient to cover the resection of the NAC, as it had stated that the technique might be modified if something unforeseen occurred during surgery. Secondly, the High Court reiterated that, according to the report from the Head of the Gynaecology Department, that particular aspect had been included in the consent form because the borders of a tumour could not be known before a histologic examination was carried out during surgery (see paragraph 12 above).

47. The Court observes that, although different from the intervention for which the applicant had initially given her consent (a quadrantectomy and right axillary lymphadenectomy), the surgical procedure which was ultimately performed was also conserving in nature, in so far as it did not entail the complete removal of the breast. However, as regards the wording of the informed consent form, the Court notes the following.

48. Although the heading and the first sentence of the form state that informed consent was being given for breast-conserving surgery, the first paragraph contains a list of possible interventions without any clear indication as to which of them were considered to be conserving procedures and which were “more aggressive” (see paragraph 6 above). In particular, one of the surgeries listed, and the only one for which the possibility of removal of the nipple was explicitly mentioned, was a simple mastectomy (complete removal of the mammary gland); according to the oncological guides

submitted by the Government, this is not considered to be conserving surgery[1].

49. Accordingly, in the Court's view, it was not sufficiently clear for a person with no medical knowledge (such as the applicant) which of the surgeries included in the list could be considered as a modification of surgical technique covered by the informed consent form. In particular, the Court considers that it was not sufficiently clear from the wording of the informed consent form that a possible modification of the scheduled technique could ultimately include a resection of the NAC and, therefore, that signing the form resulted in accepting that outcome as a possibility.

50. Secondly, the High Court considered that the applicant had accepted by signing the consent form that she was satisfied with the information received and that she had understood the scope and the risks of the intervention. However, its judgment contains no analysis of whether the applicant had indeed been informed of the specific possibility of having her NAC resected during the surgery. While it is true that the informed consent form and the medical file state that the applicant had had the opportunity to have her doubts clarified by the doctors (see paragraphs 6-7 above), the nature of those doubts and the additional explanations given are not reflected in any document. In particular, the third paragraph of the informed consent form, which contains a space to be filled in concerning the risks or complications in the patient's specific situation, was left blank (see paragraph 6 above). It is thus not possible to determine what information was actually provided to the applicant when her consent to the intervention was sought (see, *mutatis mutandis*, *Mayboroda,* cited above, § 60). In the Court's opinion, the mere fact that the applicant was able to have her doubts clarified in an undocumented interview, with no indication that the possibility of a NAC resection was ever discussed with her, is insufficient to demonstrate that she was aware of that possibility and had indeed consented to it. However, the domestic courts took no steps to clarify whether the applicant had actually been informed of that possibility (see, *mutatis mutandis*, *Reyes Jimenez*, cited above, § 35).

51. Thirdly, the Court notes that the High Court did not examine the applicant's allegation regarding the foreseeability of having her NAC resected during the surgery and the related duty of the doctors to inform her of that possibility when obtaining her consent (see paragraph 15 above).

52. The Court reiterates in this regard that, under domestic law, where written consent is required, the consent form should contain sufficient information regarding the procedure and its risks to enable the patient to make an informed decision. Doctors are under an obligation to provide information on the expected consequences, the risks likely to occur under normal

[1] Oncoguía SEGO [*Sociedad Española de Ginecología y Obstetricia*]: Cáncer infiltrante de mama. Guías de práctica clínica en cáncer ginecológico y mamario. Publicaciones SEGO, June 2017; Fundación OncoSur, Guía OncoSur de Cáncer de Mama, 2020.

conditions that are directly related to the proposed intervention, and the risks relating to the patient's circumstances (see paragraph 26 above).

53. For its part, the Oviedo Convention requires doctors to inform patients about the purpose and nature of the medical intervention at issue, as well as of its risks and consequences (see paragraph 27 above). According to the Explanatory Report to the Oviedo Convention, a patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone. In order for their consent to be valid, the persons in question must have been informed about the relevant facts regarding the intervention being contemplated. This information must include the purpose, nature and consequences of the intervention and the risks involved. The information on those risks must cover the risks inherent in the intervention and any risks related to the individual characteristics of each patient.

54. The Court observes in this connection that the informed consent form in the applicant's case referred to the possibility of obtaining a final diagnosis during the surgery through an anatomopathological examination (see paragraph 6 above), as indeed occurred in the applicant's case (see paragraph 8 above). According to the report by the Head of the Gynaecology Department, in oncological surgery it is difficult to know before the operation how far the tumour has invaded the adjacent tissues or organs, and this was indeed the reason why the informed consent form included a sentence allowing for the modification of the intervention (see paragraph 12 above). Furthermore, the same report stated that the applicant had an elevated risk of recurrence, which justified the intervention performed.

55. That being so, it appears that the need to extend the margins of the resection – in order to ensure the success of the intervention – is a possible scenario in this kind of operation.

56. Given the nature and purpose of breast-conserving surgery, the general risks and consequences associated with it and with incomplete tumour extirpation, and the applicant's specific circumstances, the Court considers that the doctors were required to duly inform her beforehand about the possibility of a NAC resection (see paragraph 33 above).

57. Moreover, such an escalation might have significant repercussions for a woman given the importance of the NAC for, *inter alia*, self-image and sexual life, and thus reinforcing the obligation to inform the patient, so that she can make an informed decision on whether to give consent to any possible removal. In the Court's opinion, the domestic courts should have been aware of this aspect, in view of the evidence before them showing that the applicant had suffered not only physical consequences, but also a serious psychological impact, resulting from the intervention in question, affecting her emotional wellbeing and sexual life (see paragraphs 15 and 17 above). Nevertheless, no

mention was made of those aspects in the domestic courts' decisions, thus omitting to take into consideration important dimensions of women's sexuality (see, *mutatis mutandis*, *Carvalho Pinto de Sousa Morais v. Portugal*, no. 17484/15, § 52, 25 July 2017).

58. Lastly, the Court notes that in this case the intervention had been planned two weeks in advance (see paragraphs 6-8 above) and that it has not been established in the domestic proceedings that the circumstances during the applicant's surgery entailed a life-threatening situation requiring urgent action on the part of the doctors (see *Y.P.*, cited above, §§ 54-55).

59. In the Court's view, the allegations raised by the applicant before the domestic courts were of significant importance in establishing the scope of the duty incumbent on the medical professionals involved in her care to seek her informed consent (see, *mutatis mutandis*, *Mayboroda*, cited above, §§ 57-58). Regrettably, the domestic courts did not scrutinise them in detail and, therefore, it cannot be said that the domestic system adequately responded to the applicant's complaint that she had not given her consent to the expansion of the scope of the surgery (see, *mutatis mutandis, Reyes Jimenez*, cited above, § 38, and *Pindo Mulla*, cited above, § 182).

60. The foregoing considerations are sufficient to enable the Court to conclude that the domestic authorities did not provide an adequate response to the applicant's claim concerning the absence of valid informed consent. Thus, the practical implementation of the existing framework was deficient and did not afford sufficient respect for the applicant's autonomy as protected by Article 8 of the Convention.

61. There has accordingly been a violation of Article 8 of the Convention.

II. APPLICATION OF ARTICLE 41 OF THE CONVENTION

62. Article 41 of the Convention provides:

> "If the Court finds that there has been a violation of the Convention or the Protocols thereto, and if the internal law of the High Contracting Party concerned allows only partial reparation to be made, the Court shall, if necessary, afford just satisfaction to the injured party."

63. The applicant did not submit a claim for just satisfaction. Accordingly, the Court considers that there is no call to award her any sum on that account.

FOR THESE REASONS, THE COURT, UNANIMOUSLY,

1. *Declares* the application admissible;

2. *Holds* that there has been a violation of Article 8 of the Convention.

Done in English, and notified in writing on 26 June 2025, pursuant to Rule 77 §§ 2 and 3 of the Rules of Court.

Martina Keller Deputy Registrar	Kateřina Šimáčková President