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		Documento di riferimento	

DECLARATION OF CONSENT
to the test to screen for
aneuploidy of chromosomes 21, 18, 13 and sex chromosomes by means of sequencing cell-free DNA in the
maternal plasma
(NIPT, Non Invasive Prenatal Testing) - singleton pregnancies and twin pregnancies

I the undersigned (Last Name, First Name)

Born in _____ on the _____

Resident in (town/city) _____ County

Street _____ no. _____ Telephone _____

Mobile phone _____ Email _____

Tax code _____

I declare that:

I have received the appropriate information on the “Test to screen for aneuploidy of chromosomes 21, 18, 13 and sex chromosomes by means of sequencing cell-free DNA in the maternal plasma”, that will be performed using CE-IVD VeriSeq™ NIPT Solution version 2 at the SOD Diagnostica Genetica (Genetic Diagnostics Departmental Organizational Unit) at Careggi University Hospital.

Furthermore, I declare that:

I have received, read and understood the document “Information on the test to screen for aneuploidy of chromosomes 21, 18, 13 and sex chromosomes by means of sequencing cell-free DNA in the maternal plasma” submitted with this declaration of consent;

I have received comprehensive information and have fully understood everything

I have been adequately informed about the nature, purpose, and methods of performance of the service offered;

I have been adequately informed about the benefits and limits of the test that I shall undergo;

I have understood that this is a screening test for aneuploidy of the chromosomes investigated, and that any high risk results must be verified by means of diagnostic tests (foetal karyotype) performed via invasive prenatal testing;

I have had the opportunity to ask questions and have received satisfactory answers;

I have had enough time to decide whether or not to agree to the test.

Therefore, freely, spontaneously and in full awareness:

☐ I AGREE

☐ I DO NOT AGREE

to the venous blood samples and the test offered

☐ I AGREE

☐ I DO NOT AGREE

to the results of the test, in the case of high risk or with insufficient FF, also being sent to the Centre of Prenatal Diagnostics indicated below

☐ I AGREE


☐ I DO NOT AGREE

to being contacted by the staff of SOD Diagnostica Genetica (Genetic Diagnostics Departmental Organizational Unit) at Careggi University Hospital and the Centre of Parental Diagnostics indicated below regarding the results of the test or for any follow ups

☐ I AGREE

☐ I DO NOT AGREE

to the test results being sent to the centre at which I underwent the combined test / ultrasound scan with evaluation of the nuchal translucence

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		Pagina	
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DECLARATION OF CONSENT
to the test to screen for
aneuploidy of chromosomes 21, 18, 13 and sex chromosomes by means of sequencing cell-free DNA in the
maternal plasma
(NIPT, Non Invasive Prenatal Testing) - singleton pregnancies and twin pregnancies

- ☐ I AGREE ☐ I DO NOT AGREE to the anonymous use of the sample that remains after the test for the standardisation of new laboratory procedures
☐ I AGREE ☐ I DO NOT AGREE to the anonymous use of the data from the test performed for the standardisation of new laboratory procedures

Finally, I declare that I understand that I can **WITHDRAW** this consent at any time prior to notification of the results.

Date _____ Signature _____

Healthcare professional who accepts the declaration

Last Name and First Name/Stamp _____-Signature

Cultural mediator (where applicable) _____ Signature

(first name, last name in block capitals and signature)

In the case of patients under 18 years of age, disqualified or subject to special care, the consent is legitimately expressed by the following authorised person (s):

Mr. / Ms. _____

Born in _____ on the ____/____/____

as (relation to patient) _____

Witness(es) (where applicable) _____ Signature

(first name, last name in block capitals and signature)

WITHDRAWAL OF CONSENT

I the undersigned _____
 on the _____

declare that I wish to **WITHDRAW** my consent to undergo the “Test to screen for the risk of aneuploidies of chromosomes 21, 18, 13 and sex chromosomes by means of sequencing cell-free DNA in the maternal plasma”

Signature _____