

General Terms and Conditions (DE-11/2018)

Preamble

- (1) Vita 34 AG (hereinafter referred to as Vita 34) pursues the collection, processing and storage of umbilical cord blood and umbilical cord tissue.
- (2) The child as the owner shall be solely entitled to the power of disposal of the umbilical cord blood preparation; the use by Vita 34 or third parties shall be excluded. Until it reaches the legal age, the persons having the care and custody (hereinafter referred to as "legal representatives") shall represent the child.
- (3) Umbilical cord blood is the foetal blood from the placenta and the attached umbilical cord that is collected immediately after the umbilical cord was cut. Umbilical cord tissue is collected by cutting the umbilical cord a second time near the placenta after the umbilical cord blood was cut and the umbilical cord blood collected. The full extent of future applications of umbilical cord blood and umbilical cord tissue cannot yet be foreseen at present.
- (4) The umbilical cord blood and umbilical cord tissue is processed and stored at the company's GMP laboratory (GMP = Good Manufacturing Practice pursuant to the EU GMP directive for medicinal products for human and veterinary use). Umbilical cord blood is subject to the German Pharmaceuticals Act (AMG). Vita 34 has the manufacturing license pursuant to § 13 AMG to collect and store umbilical cord blood and the manufacturing licenses pursuant to § 20b and 20c AMG to collect and store umbilical cord tissue. The collection of umbilical cord blood and umbilical cord tissue requires the availability of a manufacturing license for the birth centre as well. If the delivery takes place in a birth centre that does not collaborate with Vita 34, Vita 34 shall be exempt from all obligations resulting from this contract, as their fulfilment has become impossible on legal grounds.

§ 1 Object of the contract

- (1) The object of this contract is the collection and preparation of umbilical cord blood and, if applicable, umbilical cord tissue, the storage of the umbilical cord blood preparation and, if applicable, the umbilical cord tissue, as well as the services included in the selected type of contract (as at 01/11/2018). Professional processing and the preparation of the transport with the purpose of release to the prescribing doctor / other user shall be an object of the contract with regard to umbilical cord blood. The therapeutic application of the umbilical cord blood and/or umbilical cord tissue preparation shall not be the object of the contract.
- (2) If the VitaPlusDonation option is selected, the data of the umbilical cord blood will be prepared in anonymous form and entered in a stem cell registry, subject to its corresponding suitability. The legal representatives shall agree to HLA typing of the child's umbilical cord blood. If the remaining assessment of the umbilical cord blood at Vita 34 has the result that the criteria for an entry in a stem cell registry are not entirely complied with, the blood will be stored according to the selected type of contract and the data not be entered in a stem cell registry. If the umbilical cord blood is identified as being a suitable transplant for a patient and is requested by a transplantation centre, Vita 34 shall ask the legal representatives or the adult child in writing, whether the umbilical cord blood is to be released as transplant (donation) or not. If the legal representatives / adult child decide in favour of donating the umbilical cord blood, the entire preparation shall be released for transplantation. In such a case, the fees paid to Vita 34 pursuant to § 4 until that time (plus the average base rate for the elapsed period of storage) shall be refunded to the legal representatives. If the legal representatives / adult child decide against the donation, the storage of the umbilical cord blood shall be continued according to the conditions as agreed and the entry in the stem cell registry deleted.
- (3) If the donation product VitaMine&Yours is selected, Vita 34 will prepare a portion of the umbilical cord blood as the child's property and a portion of the umbilical cord blood for public (allogeneic) donation. The costs for this preparation are included in the contract fee. Once received in the laboratory by Vita 34, the collected umbilical cord blood is divided into two preparations, prepared separately (a portion for own provision and a portion for donation), and subjected to all the required tests. If the portion for donation is suitable, it is stored for public donation, and the anonymized data is recorded in a public stem cell registry. The legal representatives consent to having HLA typing performed on the child's umbilical cord blood. By concluding this contract, the child's legal representatives hereby consent to transferring ownership of one of the two blood preparation portions to Vita 34 if the weight required for receipt is met. If the required criteria for VitaMine&Yours are not met, then Vita 34 prepares the umbilical cord blood entirely as a personal provision for the child.

§ 2 Obligations of Vita 34

- (1) Vita 34 shall assume the following duties towards the child in connection with the collection of umbilical cord blood and umbilical cord tissue and the storage of the umbilical cord blood preparation:
 1. The overall responsibility for the collection of umbilical cord blood.
 2. The delivery of a collection kit.
 3. The assignment of the selected birth centre or attending physician or freelance midwife (hereinafter referred to as the person collecting the umbilical cord blood) collaborating with Vita 34 in Germany with the collection of the umbilical cord blood. The assignment will also include the instruction to abstain from collecting the umbilical cord blood at one's own discretion, if this is required from a medical point of view to protect the health of mother and child.
 4. The transport of the umbilical cord blood from the birth centre to the facility of Vita 34.
 5. The testing of the umbilical cord blood upon receipt for its suitability for preparation.
 6. a) The preparation, cryo-preservation, and storage of the umbilical cord blood preparation.
 - b) The issue of a certificate of storage.
 - c) The quality control of the umbilical cord blood preparation pursuant to the legal requirements in Germany.
 7. The professional processing and preparation of the transport with the purpose of the physician / other user after repeated testing of the umbilical cord blood preparation; free transport to any centre of application in Germany.
 8. The rendering of the services included in the selected type of contract (as at 01/11/2018).
 In case umbilical cord tissue is stored, the items 1 to 6 and 8 shall be accordingly applicable.
- (2) If the tests pursuant to § 2 sec. 1 no. 5 have the result that the preparation of the umbilical cord blood is impossible or not justifiable, Vita 34 shall inform the legal representatives in writing and destroy the umbilical cord blood. In case of the additional storage of umbilical cord tissue, the preparation and storage of the umbilical cord tissue shall also be effected if the umbilical cord blood has to be destroyed for the reasons given in clause 1, if there are no other opposing reasons and in particular, if tissue was collected in a sufficient quantity and quality.

- (3) Vita 34 may use reliable subcontractors to fulfil its obligations.
- (4) In case Vita 34 becomes insolvent, a special insurance is provided to ensure the continued storage of the umbilical cord blood and/or umbilical cord tissue for 50 years from the initial storage.

§ 3 Obligations of the mother, the legal representatives / consent

- (1) The mother or the legal representatives shall
 1. Truthfully and thoroughly complete and sign the following forms submitted by Vita 34 and return them to Vita 34:
 - 1) Medical history form until the birth
 - 2) Copy of maternity card until the birth
 - 3) Follow-up medical history form 14 days after the birth at the latest
 - 4) Information and declaration of consent depending on the selected contract variant
 - 5) Consent form regarding tissue typing pursuant to German Genetic Diagnosis Act, if contract option VitaPlusDonation or VitaMine&Yours is selected.
 2. Select only a birth centre collaborating with Vita 34, indicate the desired collection of umbilical cord blood and, if applicable, umbilical cord tissue again to the physician / midwife as well as hand the collection kit and the original deed of release provided by Vita 34 over to the person collecting the umbilical cord blood and, if applicable, the umbilical cord tissue immediately before the birth pursuant to § 7, section 2, clause 2.
 3. Promptly notify Vita 34 in writing of the name/s of the child/children after the birth.
 4. Promptly notify Vita 34 of blood-borne infectious diseases of the mother or the child occurring within twelve months after the birth (e.g. hepatitis B, hepatitis C, or HIV).
- (2) The legal representatives shall consent to umbilical cord blood being collected after the cord of the child / children was cut. If the contract type VitaPlusCord is selected, this consent shall apply to the collection of umbilical cord tissue as well.
- (3) The mother shall agree that a blood sample is taken from her to do the necessary infection-serology tests (including HIV) at the time of the birth (± 48 h).
- (4) The legal representatives shall agree that the physician / midwife / clinic submits the findings / data obtained during the pregnancy / birth to Vita 34. This shall apply as well to findings obtained after transplantation of umbilical cord blood and/or umbilical cord tissue cells. The legal representatives shall release the medical personnel from their obligation to confidentiality in this respect. The legal representatives shall agree that Vita 34 submits findings obtained by Vita 34 (except the results of the preventive screening examination) as well as copies of medical documents to the attending gynaecologist and / or physician at the clinic and that Vita 34 complies with the statutory obligations to report specific medical parameters.
- (5) If the contract option of a preventive screening examination is selected, the legal representatives shall agree that molecular-genetic diagnostic tests (preventive screening examination) are performed with the child's umbilical cord blood in accordance with the given parameters. This consent can be revoked at any time with effect for the future. The legal representatives shall be entitled not to acknowledge the examination results or parts of such results and to have them destroyed. The legal representatives shall agree to the storage of the examination material for verification of the results; this sample shall be destroyed after ten years. The legal representatives shall furthermore agree that the laboratory submits the results of the analysis in confidence to Vita 34.

§ 4 Payment

- (1) Vita 34 shall receive a contract fee and an annual fee pursuant to the selected type of contract for the storage of a child's umbilical cord blood and, if applicable, umbilical cord tissue according to the current price list. Vita 34 guarantees the amount of the annual fee for the first 20 years from the initial storage of the umbilical cord blood or umbilical cord tissue. As of the 21st year, Vita 34 shall reserve the right to adjust the annual fee in accordance with the officially established rate of price increase and increased relevant taxes that have accumulated since the beginning of the storage and to make this adjustment again after the expiry of five years respectively. If the annual fee for the first 25 years or the first 50 years is paid in advance, Vita 34 shall reserve the right to adjust the annual fee as of the 26th year or the 51st year in accordance with the officially established rate of price increase plus increased relevant taxes that have accumulated since the beginning of the storage and to make this adjustment again after the expiry of five years respectively.
- (2) A down payment on the contract fee at the amount of 195 Euro is charged for each child upon conclusion of contract. After the successful storage, the invoice of the respective remainder of the contract fee is issued. Vita 34 will debit the annual fee directly from the given bank account every year in advance. If payment by instalments was agreed, the total receivables shall become due for payment, once two successive instalments were not paid on schedule.
- (3) In case of multiple births, the full contract fee pursuant to sec. 1 will be charged for child 1 and only 50 percent of the contract fee for child 2; as of child 3, the contract fee shall be inapplicable. A down payment of 195 Euro is invoiced for child 1 and child 2. The annual fee must be paid for each stored preparation. If only one umbilical cord blood preparation can be stored, the annual fee or the compact price for child 1 plus the annual fee as of the initial storage of the umbilical cord blood or as of the child's 25th birthday (VitaPlus25 or VitaPlusCord25) or as of the child's 50th birthday (VitaPlus50 or VitaPlusCord50) will be charged.
- (4) If the contract fee and, if applicable and depending on the selected type of contract, the annual fee is not paid within three months after the due date despite a request for payment, Vita 34 shall be entitled to cancel the contract and to destroy the umbilical cord blood and/or umbilical cord tissue preparation with eight weeks prior notice.
- (5) Discounts and other benefits granted by Vita 34 (e.g. loyalty bonuses, special conditions for multiple births) cannot be combined with each other, do not apply to the down payment and are not granted with retroactive effect.
- (6) If payment by instalments is required, financing by a partner bank is a possible option. The decision on the financing shall be made at the bank's sole discretion.

§ 5 Contract period / cancellation / termination

- (1) The term of the contract shall be unlimited and is in particular not limited to the storage periods in accordance with down payments made (VitaPlus25 or VitaPlusCord25 or VitaPlus50 or VitaPlusCord50).
- (2) The legal representatives may cancel the contract in text form without stating reasons with effect of the child's next birthday.
- (3) The regular cancellation by Vita 34 shall be excluded. This shall not affect the right of extraordinary cancellation for cause of Vita 34 (e.g. default of payment pursuant to § 4).

- (4) If the contract is cancelled by the legal representatives, neither the claim of Vita 34 for payment of the full contract fee and the annual fee already incurred until the time of the cancellation shall expire nor does a claim for refund or reimbursement of the down-payment exist.
- (5) The contract shall be terminated automatically, without a notice of cancellation being required, if
 1. Urgent medical reasons in terms of the legal regulations prevent the storage of the umbilical cord blood or umbilical cord tissue before the collection. Vita 34 shall notify the parents of this in writing.
 2. The person collecting the umbilical cord blood or umbilical cord tissue refuses to execute the collection of umbilical cord blood and/or umbilical cord tissue or refrains from the collection at his/her own discretion (§ 2 sec. 1 no. 3) or other reasons prevent the collection of umbilical cord blood or umbilical cord tissue.
 3. The tests upon receipt of the umbilical cord blood and umbilical cord tissue pursuant to § 2 sec. 1 no. 5 show that a preparation is impossible or not justifiable pursuant to § 2 section 2.
 4. The reasons for termination pursuant to no. 1 or no. 3 shall not apply to the contract type VitaPlusCord, if the preparation and storage of one of the products umbilical cord blood or tissue) is possible in compliance with the quality requirements. If the storage of umbilical cord blood or tissue is to be continued, the amount of the contract fee for the storage of umbilical cord tissue in such a case shall comply with contract fee for the storage of umbilical cord blood minus the down payment made at the amount of 195 Euro and, if applicable, plus the annual fee according to the selected type of contract.
- (6) In case the contract is terminated pursuant to sec. 5, no. 1 to 3, Vita 34 shall receive only the down payment at the amount of 195 Euro. This shall not apply to cases as described in sec. 5, no. 4 (VitaPlusCord), to which the provisions stipulated therein shall apply.
- (7) If a contract of the type VitaPlusCord is cancelled, the storage of umbilical cord blood and umbilical cord tissue may be cancelled separately. The amount of the annual fee for the respectively remaining storage complies with the annual fee for the storage of umbilical cord blood. The contract fee shall not be refunded.
- (8) In case a contract with the option of preventive screening examination is terminated pursuant to sec. 5, no. 3, an additional fee at the amount of 390 Euro, VAT included, shall be paid to Vita 34 for each child for the provided findings of the preventive screening examination. This shall also apply to multiple births.
- (9) If the contract is terminated pursuant to sec. 2, 3, 4, 5, and/or 7, the legal representatives shall agree that Vita 34 destroys the umbilical cord blood and/or umbilical cord tissue, unless the child disposes otherwise of the umbilical cord blood and/or umbilical cord tissue within eight weeks after the contract has ended pursuant to § 48 German Medical Preparations Act.
- (10) Apart from the above stipulations, the contract shall terminate and thus the obligation to pay the annual fees, if Vita 34 submits the stored umbilical cord blood preparation to the attending physician upon his/her request. If the contract type VitaPlusCord was selected and only the umbilical cord blood preparation is released, the annual fee for the continued storage of the umbilical cord tissue preparation shall comply with section 7 as above.

§ 6 Assignment of claims

The legal representatives shall agree that Vita 34 may assign all outstanding claims against them in whole or in parts and disclose the data required for this purpose as well as submit the required documents. The information and documents will be treated as strictly confidential and not abused.

§ 7 Liability of Vita 34 / waiver of claims against the clinic

- (1) Vita 34 shall be liable for the object of the contract as given in § 1 clause 1 in accordance with the legal regulations.
- (2) Vita 34 shall not assume any liability whatsoever for current or possible future applications of the umbilical cord blood or umbilical cord tissue preparation, which are not the object of the contract in accordance with § 1 clause 2.
- (3) On their own behalf and in the name of the child, the legal representatives shall waive any claims against the birth centre or the person collecting the umbilical cord blood and/or the umbilical cord tissue and the maternal blood, unless such claims are based on deliberate intention. For this purpose, they submit the signed original deed of release to the birth centre. This deed shall not affect any claims of the child against Vita 34 due to negligence of the person collecting the umbilical cord blood and/or the umbilical cord tissue.
- (4) If the umbilical cord blood or umbilical cord tissue or the stem cell preparation made of umbilical cord blood or umbilical cord tissue is accidentally and/or unintentionally destroyed or otherwise made unusable, the liability of Vita 34 AG shall be limited to compensation of the additional cost of a possible autologous donation (e.g. cell separation, bone marrow) or allogeneic donation (e.g. cell separation, bone marrow). Further liability claims shall not be applicable. Vita 34 is in particular not liable for possibly missed therapeutic chances.

§ 8 Data protection

- (1) Vita 34 shall be authorised to store the personal data of the child and the legal representatives that are necessary to implement the contract and to pass them on to contractual partners where required to implement the contract. Vita 34 shall treat these data as confidential and commit its contractual partners to confidentiality.
- (2) Vita 34 shall be authorised to pass the data, which are necessary to apply the umbilical cord blood for therapeutic purposes to the physician / other user upon request.
- (3) If the donation products VitaPlusDonation or VitaMine&Yours are selected, Vita 34 will only transfer data on the preparations – and not personal data – to the stem cell registry or, if released, to the examining physician.

§ 9 Final provisions

- (1) The parties shall notify each other promptly in writing of changes of address or name. The legal representatives shall furthermore notify Vita 34 promptly of changes in the representation relationships. This shall include the notification of the child's new address details when he/she reaches the legal age.
- (2) The assignment of this contract or of obligations or rights resulting from this contract by Vita 34 to a third party shall require the written consent of the legal representatives, unless an affiliated company of Vita 34 in terms of § 15 German Stock Companies Act is concerned.
- (3) Should a provision of this contract be invalid or impracticable, this shall not affect the validity of the remaining provisions. The parties shall undertake to replace the invalid or impracticable provision by such a valid and practicable provision that comes closest to the originally intended purpose of the invalid or impracticable provision. The same shall apply to contractual gaps.
- (4) The laws of Germany shall apply.

Information on the right of withdrawal

Right of withdrawal

You may withdraw from this contract without stating any reasons within fourteen days.

The period of withdrawal is fourteen days and starts with the date on which the contract is concluded.

To exercise the right of withdrawal, you need to submit an explicit declaration (sent e.g. by mail, fax, or email) of your decision to withdraw from this contract to **Vita 34 AG, Perlickstrasse 5, D-04103 Leipzig, phone: +49 (0)341 48792-0; fax: +49 (0)341 48792-20, email: kundenservice@vita34.de**. To comply with the period of withdrawal, it is sufficient to send the declaration on the withdrawal prior to the expiry of this period.

Consequences of withdrawal

If you withdraw from the contract, we shall reimburse any payment made by you, including the cost of delivery (except for the additional cost arising from your choice of another than the low priced standard type of delivery), promptly and at the latest within fourteen days after we received the declaration of withdrawal. We will use the same means of payment that you used for the initial transaction, unless otherwise expressly agreed. We will in no event charge extra costs for such reimbursement.

You have to return the goods (the collection kit) promptly and in any case at the latest within fourteen days after you informed Vita 34 about your withdrawal to **Vita 34 AG, Perlickstrasse 5, D-04103 Leipzig**. This period shall be regarded as complied with, if you send the goods prior to the expiry of this period.

You will bear the charges for the return.

You need to pay for a possible depreciation of the goods only, if this depreciation is the result of you handling the goods in way that is not required to check the quality, properties, and functionality of the goods.

If you requested that the services start during the period of withdrawal, you have to pay an adequate amount corresponding to the portion of the services already rendered at the date on which you informed us about your decision to withdraw from the contract compared to the total scope of services provided for in the contract.

End of information on right of withdrawal

Withdrawal (Please fill in only if you want to withdraw from the contract!)

I/we herewith withdraw from the contract I/we concluded regarding the purchase of the following goods/the provision of the following services:

Date of order* _____

Name/address of consumer(s) _____

Title* _____ First name* _____ Last name* _____

Street and house number* _____

ZIP code and place* _____

Country _____

Your email address so that we can promptly confirm the receipt of your declaration of withdrawal.

Your email address* _____

Date of withdrawal* _____

Signature* _____

All fields marked with an asterisk (*) are required.