

General Terms and Conditions VitaPur (DE-11/2018)

Preamble

- (1) Vita 34 AG (hereinafter referred to as Vita 34) pursues the collection, processing, and storage of stem cells from umbilical cord blood.
- (2) The child as the owner shall be solely entitled to the power of disposal of the stem cell deposit; 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 remaining umbilical cord that is collected immediately after the umbilical cord was cut. The full extent of future applications of umbilical cord blood cannot be foreseen yet at present.
- (4) The umbilical cord blood 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) and the German Pharmaceuticals Act (AMG). Vita 34 has the manufacturing license pursuant to § 13 AMG to collect and store umbilical cord blood. The collection of umbilical cord blood requires the availability of a manufacturing license for the birth centre as well. That is why the collection of cord blood shall be excluded, if the delivery takes place in a birth centre that does not collaborate with Vita 34. In such a case, 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 the storage of the umbilical cord blood preparation as specified in the selected type of contract „VitaPur“ (as at 1-11-2018). Professional processing and the preparation of transportation with the purpose of release to the prescribing doctor/other user shall be another object of the contract with regard to umbilical cord blood. The therapeutic application of the umbilical cord blood preparation shall not be the object of the contract.
- (2) The stem cells will be provided in a public donation. Subject to the adequate suitability, the data of the umbilical cord blood will be prepared in anonymous form and entered in a stem cell registry. The legal representatives shall agree to HLA typing of the child's umbilical cord blood. If the remaining assessment of the umbilical cord blood by Vita 34 has the result that the criteria for an entry in a stem cell registry are not fully complied with, the blood will be stored without being registered in a stem cell registry. In that case, public donation shall be regarded as not selected. 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 legally capable or adult child in writing, whether the umbilical cord blood is to be released for transplantation (donation) or not. If the legal representatives / legally capable or 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 / legally capable or 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.

§ 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 the storage of the umbilical cord blood preparation according to the type of contract „VitaPur“ (as at 1-11-2018):
 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 transportation of the umbilical cord blood from the birth centre to the facilities 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 transportation with the purpose of delivery to the physician / other user after repeated testing of the umbilical cord blood preparation.
 8. The input of anonymised data in a stem cell registry as agreed and if suitable pursuant to § 1, section 2.
- (2) If the tests pursuant to § 2, sec. 1, sub-sec. 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 this regard in writing and destroy the umbilical cord blood.
- (3) Vita 34 may use reliable subcontractors to fulfil its obligations.

§ 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
 - 5) Consent form regarding tissue typing pursuant to German Genetic Diagnosis Act.
 2. Select only a birth centre collaborating with Vita 34, indicate the desired collection of umbilical cord blood 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 immediately before the birth pursuant to § 7, section 3, 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, which can be transferred by blood, 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.

- (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 the umbilical cord blood. 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 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.

§ 4 Payment

- (1) Vita 34 shall receive a contract fee and an annual fee pursuant to the selected type of contract "VitaPur" for the storage of a child's umbilical cord blood according to the current price list.
- (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.
- (3) Payment of invoices will be made by direct debit exclusively. By acknowledging the present general terms and conditions, the legal representatives shall authorise the direct debit scheme. The legal representatives have at least ten workdays between the receipt of the invoice and the direct debit of the invoiced amount to check the invoice and, if necessary, provide for sufficient coverage of the account.
- (4) If the contract fee and the annual fee are 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 preparation after eight weeks prior notice.
- (5) Discounts and other benefits granted by Vita 34 (e.g. special conditions for multiple births) shall be excluded.

§ 5 Contract period / cancellation / termination

- (1) The term of the contract shall be unlimited and has a minimum duration of 10 years.
- (2) The legal representatives may cancel the contract in writing without stating reasons with effect of the child's next birthday after ten years at the earliest. This shall not affect the right of extraordinary cancellation for cause.
- (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 before the collection. Vita 34 shall notify the parents of this in writing.
 2. The person collecting the umbilical cord blood refuses to execute the collection of umbilical cord blood or refrains from the collection at his/her own discretion (§ 2, sec. 1, sub-sec. 3) or other reasons prevent the collection of umbilical cord blood.
 3. The tests upon receipt of the umbilical cord blood pursuant to § 2, sec. 1, sub-sec. 5 show that a preparation is impossible or not justifiable pursuant to § 2, section 2.
- (6) In case the contract is terminated pursuant to sec. 5, sub-sec. 1 to 3, Vita 34 shall receive only the down payment at the amount of 195 Euro.
- (7) If the contract is terminated pursuant to sec. 2, 3, 4, 5, the legal representatives shall agree that Vita 34 destroys the umbilical cord blood, unless the child disposes otherwise of the umbilical cord blood within eight weeks after the contract has ended pursuant to § 48 German Medical Preparations Act.
- (8) 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.

§ 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 be 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 preparation, which are not the object of the contract in accordance with § 1, clause 3.
- (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 the maternal blood, unless such claims are based on deliberate intention or gross negligence. For this purpose, they shall 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.
- (4) If the umbilical cord blood or the stem cell preparation made of umbilical cord blood is destroyed or otherwise made unusable due to negligence, 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 such 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) Within the scope of public donation, Vita 34 will pass on only the data of the preparation, however, no personal data, to the stem cell registry or to the applying physician in case of release for application.

§ 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 obligations or rights resulting from this contract by Vita 34 to a third party shall require the written consent of the legal representatives or the legally capable child, 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.
- (5) In case of doubt, the German version of the present General Terms and Conditions shall have priority.

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.