



Letter of Intent

PVC free blood transfusion at Karolinska University Hospital

The project PVCfreeBloodBag¹ has demonstrated that it is possible to produce a completely PVC free set of four bags with the ability to store red blood cells. The set of bags have fulfilled our requirement specifications² including a gap analysis for CE-marking.

The majority of Swedish healthcare and other healthcare organisations stand behind this initiative and now Karolinska University Hospital is taking the next step in strive for a PVC free blood processing and storage system.

Currently, blood bags for red blood cells are made of PVC, which requires a plasticizer, to become soft. Plasticizer can transfer from the bag into the blood. This is problematic, because the most common plasticizer is the phthalate DEHP. This substance is classified as toxic to reproduction and has recently also been classified as an endocrine disrupting chemical, EDC. We have chosen a plastic that does not need a plasticizer to become soft. There are alternative plasticizers on the market, but we cannot predict the consequences of those, so we chose PVC-free as a precaution – to avoid risks due to new plasticizers. Of course, no other substances harmful to health should be added. There are several benefits to a new bag; most important in terms of healthcare is minimized patient exposure to potentially hazardous substances. The youngest patients are the most vulnerable ones. We are all exposed to endocrine disruptors from multiple sources, but healthcare should not be one of these. If we get rid of EDC's, in the long run we will have healthier populations and long-term healthcare costs. The focus is on improving conditions for health and environmental performance, whilst maintaining levels of medical quality and safety.

Further improvements and evaluations are necessary before market introduction, but an increased demand will facilitate market introduction.

We as a provider of healthcare intend to purchase PVC free blood bags, provided that they have the equivalent performance as regards safety, quality and functionality, nor do they differ significantly from current price levels for the products that are now available on the market.

Name:.....

Date:.....

Organisation:.....

*Send signed document to the environmental department, who is collecting "Letter of intent" on behalf of Karolinska University Hospital.
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¹ www.pvcfreebloodbag.eu

² Requirement specifications are found as appendix 1 in the pre study.