

When **CHANGE**
means
NO COMPROMISE

THE DEHT SOLUTION: SAFER, EFFICIENT AND RELIABLE.

Our **vision**

Macopharma is committed to addressing the health concerns related to the DEHP plasticizer used in medical devices.

Our priority is to support healthcare professionals by providing reliable solutions designed to ensure high-quality blood components, for the benefit of both donors and patients.

As part of this commitment, we offer blood bag systems in compliance with Regulation (EC) No 1907/2006 (REACH).

Moving from **P to T: changing one letter, making a meaningful difference**

In its search for alternative plasticizers, Macopharma selected **DEHT** as a solution aligned with its commitment.

No compromise *on...*

HEALTH AND SAFETY:

Patients transfused using **PVC-DEHT devices** are significantly less exposed to plasticizers than when using a PVC-DEHP devices, regardless of the blood component transfused. For RBCs, regardless of the preservative solution used, the DEHP-equivalent concentrations are **50% higher** than those of DEHT, throughout the storage at **Day 49**¹.

PERFORMANCES :

Whole blood-derived RBC, collected and stored in **DEHT/PAGGSM** collection bags, maintained acceptable quality through **42 DAYS** of storage.

100% of DEHT/PAGGSM units were **compliant with the EDQM** requirements².

BUSINESS CONTINUITY:

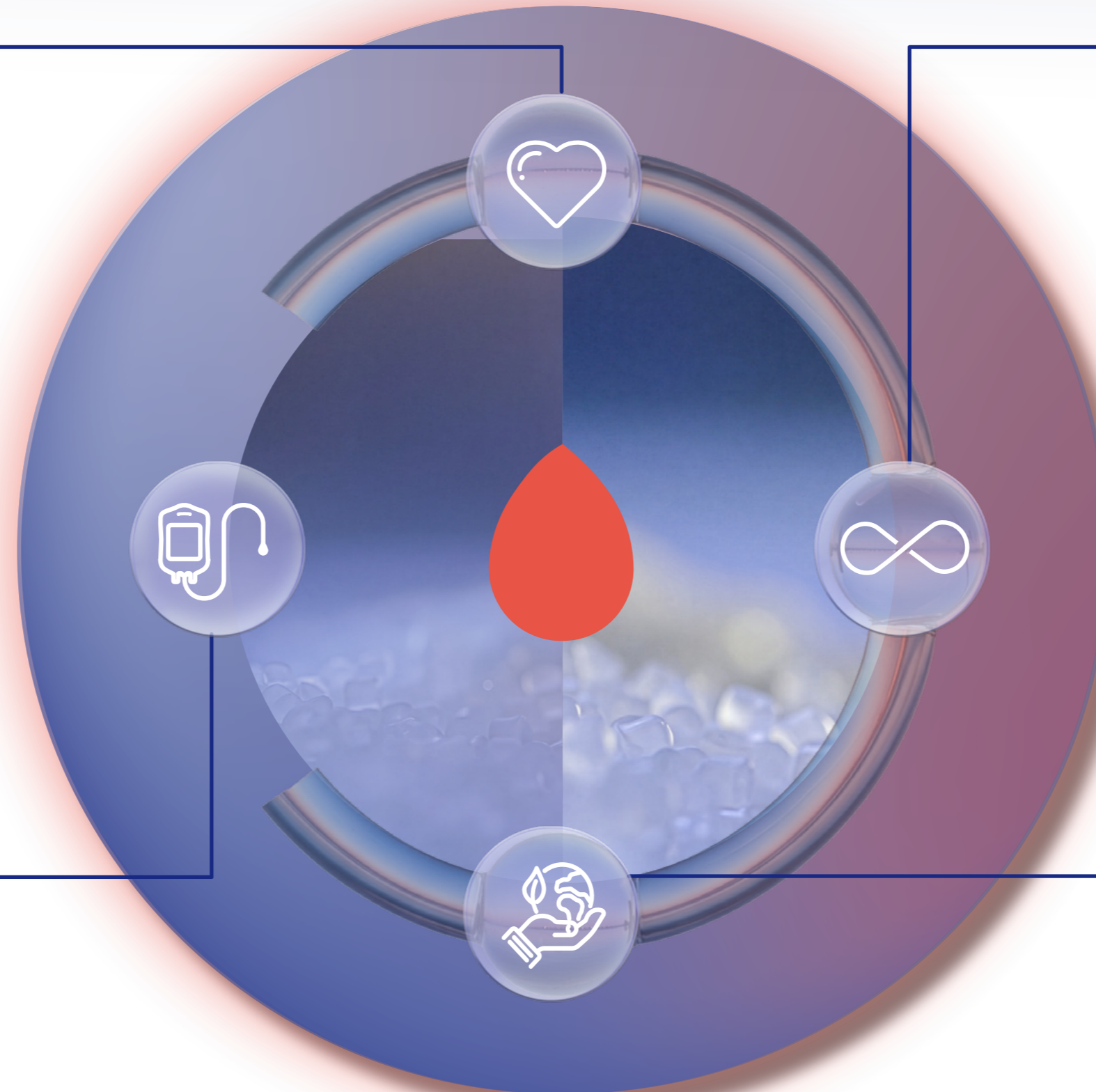
More than 4 DEHT suppliers operate worldwide reducing the risk of material shortage and ensuring operational continuity.

We collaborate closely with our suppliers to ensure a seamless transition from DEHP to DEHT, while guaranteeing uninterrupted product availability throughout the process.

SUSTAINABILITY:

DEHT has been shown to be **less environmentally toxic** than DEHP, demonstrating that switching to this new plasticizer will improve its **environmental performance**.

Macopharma will continue its efforts to minimize its environmental impact by working on raw material sourcing and processing³.



Our solution

DEHT

- Low toxicological profile^{4,5}
- Low leaching in blood components¹
- Improves patients safety by reducing plasticizer exposure during transfusion¹
- Compliant with EU regulation



PAGGSM

- Preserves cellular integrity and morphology^{6,7}
- Reduces the risk of haemolysis^{6,7}
- Allows quality and efficacy of stored blood components^{6,7}
- Well-known additive solution recognized for enhancing RCC storage performance

Providing :

- 1 unit of Leukodepleted Red Cell Concentrate $<1 \times 10^6$ rWBC/Unit
- 1 unit of Plasma
- 1 unit of Buffy Coat*



Proven performances

Our new **DEHT/PAGGSM in-line RCC filter** system has been validated in pre-clinical studies, with results shown below :

	CBS/NETCAD ⁸	EFS/SFS ⁹			EDQM requirements	
Day of storage	43	42	49		-	
Haemolysis (%)	0.33 ± 0.12	0.22±0.09	0.28±0.07	0.30±0.15	0.35±0.06	< 0.8 % in ≥ 90% of units
Hct (%)	61.4±2.6	59±3			50 - 70	
Hb (g/unit)	52.0±5.0	50.2±6.3			≥ 40	
Residual WBC (x10 ⁶ rWBC/unit)	0.08	0.06 ± 0.05			<1x10 ⁶ rWBC/unit	

Your standards *remain* our standards.

Our solutions continue to support up to **42 days** of red blood cell storage in **accordance with EDQM requirements**.



As we embrace change,

we remain fully dedicated to ensuring that this transition has no impact on your daily practices or outcomes.

You can expect **greater patient safety without compromising on quality, performance and processes** all aligned with your requirement.

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macopharma

We support life



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