Gliwice, 04.08.2026

Statement e-2201N/1/2026

The adhesive used in the self-adhesive material with reference number e-3057N is intended for the reverse coating of labels used for the **labelling of blood bags**.

According to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, blood bags are considered medical devices of class IIb.

The adhesive grade has been tested according to **EN ISO 3826-1 "Plastics Collapsible Containers for Human Blood and Blood Components – Part 1: Conventional containers"**, paragraph 8.5 (label requirements), for a potentially harmful effect on the contents of the blood bag.

Additionally, an evaluation of the substances used in the adhesive grade based on their toxicological properties and a migration analysis of the adhesive components into the contents of the blood bags were performed.

Based on the results of the formulation evaluation and migration analyses, the adhesive grade does not have a harmful effect on the contents of blood bags, and the requirements of the above-mentioned standard are met.

Damian Janiga

Etisoft Sp. z o.o.
ul. Szara 21
44-100 Gliwice