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2 July 2021

Dr. Dr/Dr-hu

**EXPERT'S OPINION****3748 GD 21**

for Roll Cover Italiana s.r.l.  
Via Lazzaretto 40  
21013 Gallarate (VA)  
Italy

Product A2

The product manufactured by the company mentioned above is an adhesive grade, which is used for the reverse coating of labels used for the labelling of blood bags.

Under

The Act on Medical Devices (Medical Devices Act) of 02.08.1994, last amended on 19 May 2020, blood bags are considered as medicine products class IIb.

The adhesive grade was tested according to the

EN ISO 3826-1 „Plastics Collapsible Containers for Human Blood and Blood Components - Part 1: Conventional containers ", state of 2020, Paragraph 8.5 label requirements (e),

for a possibly harmful effect on the content of the blood bag.

Additionally, an evaluation of the employed substances of the adhesive grade based on their toxicological properties as well as a migration analysis of the adhesive components in the content of the bags was performed.

With regard to the results of the formulation evaluation and the analyses it can be derived that the adhesive grade does not have a harmful effect on the content of blood bags and that the requirements of the standard mentioned above are met in this case.



Öffentlich anerkannter Sachverständiger  
zur Untersuchung der Gegenproben von  
Verpackungsmitteln aus Papier, Pappe,  
Kunststoffen, Glas, Metallblech und  
sonstigen Metallverpackungen auf ihre  
Lebensmitteltechnische Unbedenklichkeit

**(Behrendt)**  
Officially certified  
and authorized food  
chemist