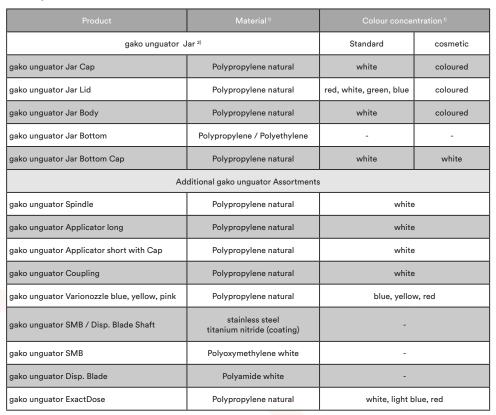
## **Declaration of Conformity**



Hereby the Gako International GmbH declares:



Gako International GmbH is DIN EN ISO 9001:2015 certified

1) Conformity declarations for materials and colour concentrates are deposited at Gako International GmbH.

2) With detailed certificate of analysis according to guideline from the Federal Union of German Associations of Pharmacists (Bundesapotheker-kammer) "Examination and Storage of primary packaging material "Prüfung und Lagerung von Primärpackmittel" 13th of November 2013) as download at unguator.com/coa and the shortened certificate of analysis on the plastic packaging.

complies with the legal requirements of plastic Regulation (EU) Nr. 10/2011 and Regulation (EC) Nr. 1035/2004 (in their current version).

For usage according to specification, both, the overall and specific migration are under the legal limits of 10 mg/dm³, according to Regulation (EU) Nr. 10/2011.

The following monomers and additives, which are subject to a specific migration limit (SML), are included, according to suppliers, in the used material:

Plastic Material		
Polypropylene natural	-	
Polyamide	Caprolactam:	SML (T) = 15 mg / kg
Polyethylene	RefNo. 68320:	SML = 6 mg / kg
	RefNo. 89040:	SML = 25 mg/kg (calculated als Zn-salt)
	RefNo. 60800:	SML = 30 mg / kg
Polyoxymethylene	Formaldehyde:	SML = 15 mg / kg
	1,3-Dioxolane:	SML = 5 mg / kg
	Trioxane:	SML = 5 mg / kg
	CAS-No. 36443-68-2:	SML = 9 mg /kg

Colour concentrate:			
White	RefNo. 13380/25600/94960:	SML = 6 mg / kg	
	RefNo. 68320:	SML = 6 mg / kg	
	Iron, Fe:	SML = 48 mg / kg	
Other colours	-	-	

Compliance with these specific migration limits is certified by the polymer manufacturers.

The traceability of the product, according the regulation (EC) Nr. 1935/2004, is ensured by the serial number.

Specification for intended use:

The above-named products are suitable to use with aqueous and acidic mediums.

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