RUMA®
Marker-System

Hauptsitz | Ruma GmbH
Wilhelm-Schlombs-Allee 1
50858 Köln

Geschäftsführerin:
Monika Wetzke

Wissenschaftliche Leitung:
Prof. Dr. Dr. R. Keller
Wissenschaftliche Begleitung:
Dr. B. Huppertz

Tel: + 49 22 1 / 3990 11 0
Fax: + 49 22 1 / 3990 11 20

info@marker-test.de
www.marker-test.de

Bankverbindung:
Stadtsparkasse Köln
SWIFT-BIC:COLSDE33
IBAN: DE48 3705 0198
1900 4021 14

Handelsregister-Nr.:
HRB 58065

USt-ID:
DE 250 38 62 10

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Statement of no objection

Regarding the marker procedure which is applied for the identification of urines, polyethylene glycole (Macrogol) is used as marker. The individual markers differ in the number of repeating units and thereby also in molecular weight and chain length.

Macrogol is used in the manufacturing of almost all drug groups, e.g. in the production of many antitussives (effervescent tablets) which are also approved for children. Furthermore, they are present in tablets and coated tablets such as garlic tablets, antihypertonics, sedatives, relaxants, pain relievers and many more. They are used as solublizers for fat-soluble substances, also externally on the skin as antidote in case of poisonous substances, as well as, on a trial basis, internally in case of tablet bolus formation.

Although the markers are used in various medical products, they themselves do not fall within the definition of pharmaceuticals as per § 2 of the German Medicines Act and are therefore not subject to approval.

Regarding a possible classification as medical device it is relevant to note that the marker substances only serve investigatory purposes. They do not have an intended use relating to medical purposes.
Presence verification of a marker substance in a urine sample only attests to the authenticity of this urine sample. It does not provide any additional medical or diagnostic information. As such, a classification as in vitro medical device is also not possible. Please refer to Article 2 of the European Medical Device Regulation (EU) 20017/745 (MDR) as well as Annex XVI of said regulation for further information.

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Upon routine inspection in accordance with Article 93 MDR in connection with § 77 Sec 1 and 2 German Medical Device Law Implementation Act (Medizinprodukte-Durchführungsgesetzt MPDG) the District Government of Cologne did not dissent from this legal opinon as per their letter dated December 17th, 2022. Already on June 26th, 2002 the District Government of Cologne confirmed in writing that the marker substances were neither subject to the definition of the German Medicines Act (Arzneimittelgesetz, AMG) nor the German Act on Medical Devices (Medizinproduktegesetzt, MPG) effective at that time and thus did not require approval.

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Monika Wetzke
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