

EU-Declaration of Conformity

according to Article 17 and Annex IV of the EU 2017/746

Manufacturer

Name: Med Auxil analysis aids e.K.

SRN: DE-MF-000027810

Address: Triftstr. 25

38723 Seesen Deutschland

Product

Name: Stool collection aid

EMDN Code: | W050180

Basic-UDI-DI: 426238948stoolcolNN

Intended purpose: The stool collection aid is an accessory for specimen

containers (in vitro diagnostics) and facilitates hygienic stool specimen collection. By using the stool collection aid, the stool can be removed directly from the stool collection aid and placed in the specimen container. This avoids the need to collect stool from the toilet, thus

avoiding contamination of the specimen.

Risk class: A

Classification rule: 5 a) accessories which possess no critical

characteristics

Common specification none Involved notified body none

We, Med Auxil analysis aids e.K., as the legal manufacturer of the medical devices listed above, declare under our sole responsibility the conformity of the products with the following requirements:

 REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

With his signature, Harald Ludewig, in his capacity as Managing Director and on behalf of Med Auxil analysis aids e.K., declares the conformity of the listed medical device with the requirements applicable within the EU.

This Declaration of Conformity is valid until: 01.02.2025

Seesen 01.02.2023 Harald Ludewig Managing Director

Place Date Name Function Signature

Valid from: 01.02.2023
Valid until: 01.02.2025
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