



**EU Declaration of Conformity  
for product Stackable Cuvette, 1ml**

**REF**

10033666

Basic UDI-DI

91201239110010DZ



**STRATEC Consumables GmbH**  
Sonystrasse 20, 5081 Anif, Austria  
SRN: AT-MF-000023689

We, as manufacturer of Stackable Cuvette, 1ml take sole responsibility for and hereby declare that Stackable Cuvette, 1ml meets the provisions of the following regulation:

- *REGULATION (EU) 2017/746 on in vitro medical devices*

**RISK Class**

A  B  C  D

The Stackable Cuvette, 1ml are validated for their intended use in combination with the KleeYa System. In their function as KleeYa accessories, they are classified as class A IVD medical devices.

**CONFORMITY ROUTE**

- ANNEX IX Technical Documentation Examination  
 ANNEX IX Full Quality System  
 ANNEX XI Production Quality System  
 ANNEX I & II + III

Conformity with the relevant General Safety and Performance Requirements is demonstrated for the Stackable Cuvette, 1ml in combination with the KleeYa System. The application of the KleeYa System for in vitro diagnostic purposes requires a separate conformity assessment according to REGULATION (EU) 2017/746 for the complete system into which it will be incorporated and / or is used in combination with (e.g. assay).

This Declaration of Conformity is valid for the product's configuration and the regulatory requirements effectual at the date the Declaration was issued. Changes affecting the product, and / or the applicable regulations trigger a review of the conformity assessment the Declaration is based on, and the issuance of a new version of the document.

Date: 2022-05-25

Place: Anif

Signature:

  
Thomas Ehrenfeld  
PRRC  
STRATEC Consumables GmbH

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