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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