EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

Aesku. Diagnostics GmbH & Co. KG Mikroforum Ring 2 55234 Wendelsheim Germany

for the scope

Rapid test for the detection of SARS-CoV-2 antigen for self-testing **AESKU.RAPID SARS-CoV-2** (REF 840001E, 840003E, 840005E, 840007E, 840003K, 840005K, 840007K)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from 2021-12-14 Valid until 2024-05-26 D1495100001 Registration no. Report no. P21-01415-214300

Stuttgart 2021-12-14

Head of Certification Body





Internet: http://www.mdc-ce.de