AESKU.DIAGNOSTICS
THE DIAGNOSTIC TOOL THAT WORKS

Declaration of Conformity

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We

Aesku.Diagnostics GmbH & Co. KG

Mikroforum Ring 2, 55234 Wendelsheim, Deutschland / Germany

declare on our own responsibility that
the in-vitro diagnostics medical product

AESKU.RAPID SARS-CoV-2
(REF: 840001/ 840003/ 840005)

meets all the provisions of the Directive 98/79/EEC which apply to it.

Applied Standards:

DIN EN ISO 13485 (Certificate Number: MD 619745)

DIN EN 13612	DIN EN ISO 17511
DIN EN 13641	DIN EN ISO 18113-2
DIN EN ISO 14971	DIN EN ISO 19011
DIN EN ISO 15223-1	DIN EN 23640
DIN EN ISO 17050	DIN EN 62366-1

Conformity assessment procedure according to

Annex III
of Directive 98/79/EEC

The in-vitro diagnostics medical products of Aesku.Diagnostics are classified as

„other products“

according to the directive 98/79/EEC

This declaration of conformity loses its validity, if changes are made without approval of the manufacturer.

Wendelsheim, 2021-05-31

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Ort, Datum / place, date

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Dr. Torsten Matthias
CEO
Aesku.Diagnostics GmbH & Co KG