



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 010051 0118 Rev. 02

Manufacturer:

Abbott GmbH

Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

Product:

Screening test for HIV-1/-2 marker

Model(s):

ARCHITECT HIV Ag/Ab Combo

Parameters:

Product Name

REF N°

ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-22
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-27
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-32
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-37
ARCHITECT HIV Ag/Ab Combo Calibrator	4J27-03
ARCHITECT HIV Ag/Ab Combo Controls	4J27-12
HIV Ag/Ab Combo Reagent Kit	4J27-74
HIV Ag/Ab Combo Reagent Kit	4J27-77
HIV Ag/Ab Combo Reagent Kit	4J27-78
HIV Ag/Ab Combo Calibrator	4J27-09
HIV Ag/Ab Combo Controls	4J27-19

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.:

713177008-2_16

Valid from:

2020-01-28

Valid until:

2024-05-26

Date,

2020-01-28

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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