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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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 103108 0006 Rev. 01

Manufacturer:

Abbott Diagnostics Medical Co., Ltd.

357 Matsuhidai
Matsudo-shi, Chiba
270-2214 JAPAN

Product:

Screening test for Hepatitis B marker

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.:

JNQ235039508

Valid from:

2019-10-30

Valid until:

2023-09-09

Date,

2019-10-30

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

Determine™ HBsAg 2 20 Test: 7D2946
Determine™ HBsAg 2 100 Test: 7D2947

Facility(ies):

Abbott Diagnostics Medical Co., Ltd. Chiba Plant
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214 JAPAN

Abbott Diagnostics Medical Co., Ltd. Chiba Logistic Center
483-2 Matsuhidai, Matsudo-shi, Chiba, 270-2214 JAPAN

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