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TÜVRheinland®

EC Design-Examination Certificate

Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60141023 0001

Report No.: 60269323 001

Manufacturer:

Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

Product Identification:

In vitro diagnostic immunoassay for the qualitative detection of total antibodies to hepatitis B core antigen.
- IMMULITE® 2000 Anti-HBc SMN-10381311 Ref-L2KHC2

Replaces certificate, registration no.: IL 60140787 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-04-30

Effective Date: 2019-07-17

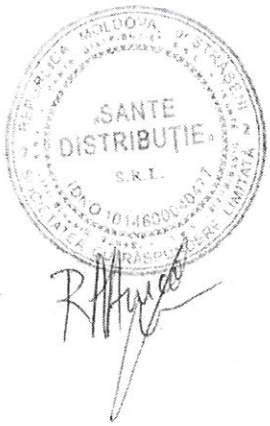
Date: 2019-07-17

Notified Body

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.



TÜVRheinland®

EC Design-Examination Certificate

Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60141028 0001

Report No.: 60269324 001

Manufacturer:

Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

Product Identification:

In vitro diagnostic immunoassay for the quantitative determination of IgM antibodies to hepatitis B core antigen.
- IMMULITE® 2000 Anti-HBc IgM SMN-10381321 Ref-L2KMC2

Replaces certificate, registration no.: IL 60140789 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-04-30

Effective Date: 2019-07-17

Date: 2019-07-17

Notified Body

Dipl.-Ing. Sven Hoffmann

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TÜVRheinland®

EC Design-Examination Certificate

Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60141026 0001

Report No.: 60269325 001

Manufacturer:

Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

Product Identification:

In vitro diagnostic immunoassay for the quantitative determination of antibodies to hepatitis B surface antigen.
- IMMULITE® 2000 Anti-HBs SMN-10381318 Ref-L2KAH2

Replaces certificate, registration no.: IL 60140788 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-04-30

Effective Date: 2019-07-17

Date: 2019-07-17

Notified Body

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜVRheinland®

EC Design-Examination Certificate
Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60141016 0001

Report No.: 60299326 001

Manufacturer:

Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

Product Identification:

In vitro diagnostic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg).
- IMMULITE® 2000 HBsAg SMN-10381306 Ref-L2KHB2

Replaces certificate, registration no.: IL 60140785 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-04-30

Effective Date: 2019-07-17

Date: 2019-07-17

Notified Body

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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EC Design-Examination Certificate

Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60141025 0001

Report No.: 60269327 001

Manufacturer:

Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

Product Identification:

In vitro diagnostic immunoassay for confirming the detection of hepatitis B surface antigen (HBsAg).
- IMMULITE® 2000 HBsAg Confirmatory Kit
  SMN-10381312 Ref-L2KCH1

Replaces certificate, registration no.: IL 60140790 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-04-30

Effective Date: 2019-07-17

Date: 2019-07-17

Notified Body

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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