



R. Mierisch



EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6

Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60145356 0001

Report No.: 60269322 004

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

Products: (see attachment for products included)

Replaces certificate, registration no.: HL 60141031 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2019-12-16

Notified Body

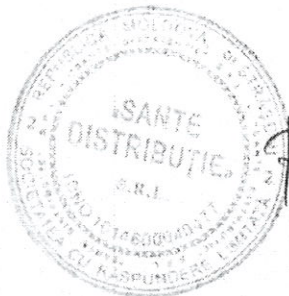
Date: 2019-12-16

K. Mierisch
Katja Mierisch



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.



Doc. 1/6, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60145356 0001
Report No.: 60269322 004

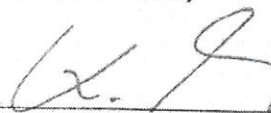
Manufacturer: Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

List A Products included:

- IMMULITE® 2000 Anti-HBc SMN-10381311 Ref-L2KHC2
- IMMULITE® 2000 Anti-HBc IgM SMN-10381321 Ref-L2KMC2
- IMMULITE® 2000 Anti-HBs SMN-10381318 Ref-L2KAH2
- IMMULITE® 2000 HBsAg SMN-10381306 Ref-L2KHB2
- IMMULITE® 2000 HBsAg Confirmatory Kit
SMN-10381312 Ref-L2KCH1
- ADVIA Centaur® Quantitative HBsAg (QHBS) Master Curve
Material SMN-10698737
- ADVIA Centaur® Quantitative HBsAg assay (QHBS)
SMN-10699087
- ADVIA Centaur® Quantitative HBsAg (QHBS) Quality Control
SMN-10699088
- Atellica® IM Quantitative HBsAg (QHBS)
SMN-11200643

Date: 2019-12-16

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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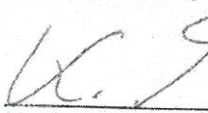
Manufacturer: Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

List A Products included:

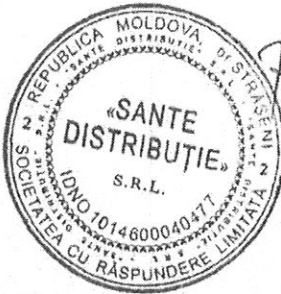
- Atellica® IM Quantitative HBsAg Quality Control (QHBS QC)
SMN-11200644
- Atellica® IM Quantitative HBsAg Master Curve Material
(QHBS MCM) SMN-11200651
- ADVIA Centaur® Anti-HBe Assay SMN-10995013
- ADVIA Centaur® Anti-HBe (aHBe) Quality Control
SMN-10995023
- Atellica® IM Anti-Hepatitis B e Antigen (aHBe)
SMN-11202933
- Atellica® IM Anti-Hepatitis B e Antigen Quality Control
(aHBe QC) SMN-11202934
- ADVIA Centaur® HBc Total 2 (HBcT2) SMN-10376698
- ADVIA Centaur® HBc Total 2 (HBcT2) Quality Control
SMN-10376699

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

List B Products included:

- IMMULITE®/IMMULITE® 1000 PSA SMN-10380949 Ref-LKPS5
- IMMULITE®/IMMULITE® 1000 PSA SMN-10380960 Ref-LKPS1
- IMMULITE®/IMMULITE® 1000 Third Generation PSA
SMN-10380956 Ref-LKUP1
- IMMULITE®/IMMULITE 1000 Free PSA SMN-10380967 Ref-LKPF1
- IMMULITE® 2000 Free PSA SMN-10380984 Ref-L2KPF2
- IMMULITE® 2000 PSA SMN-10380986 Ref-L2KPS2
- IMMULITE® 2000 PSA SMN-10380996 Ref-L2KPS6
- IMMULITE®/IMMULITE® 1000 PAPP-A SMN-10381150 Ref-LKPC1
- IMMULITE®/IMMULITE® 1000 HCG SMN-10381161 Ref-LKCG1
- IMMULITE®/IMMULITE® 1000 AFP SMN-10381162 Ref-LKAP1

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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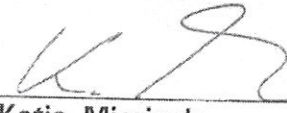
Manufacturer: Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

List B Products included:

- IMMULITE®/IMMULITE® 1000 Free Beta HCG
SMN-10381164 Ref-LKBCG1
- IMMULITE®/IMMULITE® 1000 Unconjugated Estriol
SMN-10381168 Ref-LKUE31
- IMMULITE® 2000 Unconjugated Estriol
SMN-10381171 Ref-L2KUE36
- IMMULITE® 2000 Unconjugated Estriol
SMN-10381192 Ref-L2KUE32
- IMMULITE® 2000 Free Beta HCG SMN-10381175 Ref-L2KFB2
- IMMULITE® 2000 AFP SMN-10381184 Ref-L2KAP6
- IMMULITE® 2000 AFP SMN-10381187 Ref-L2KAP2
- IMMULITE® 2000 HCG SMN-10381194 Ref-L2KCG6
- IMMULITE® 2000 HCG SMN-10381206 Ref-L2KCG2
- IMMULITE® 2000 PAPP-A SMN-10381213 Ref-L2KPC2
- IMMULITE®/IMMULITE® 1000 Toxoplasma Quantitative IgG
SMN-10381268 Ref-LKTXP1

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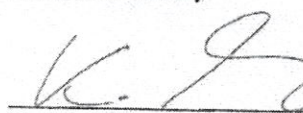
Manufacturer: Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
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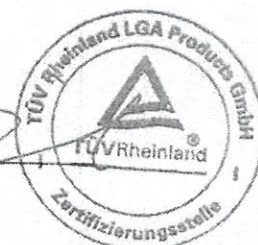
List B Products included:

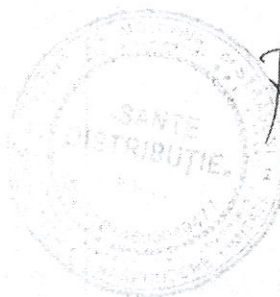
- IMMULITE®/IMMULITE® 1000 Rubella IgM
SMN-10381282 Ref-LKRM1
- IMMULITE®/IMMULITE® 1000 Toxoplasma IgM (μ -Capture)
SMN-10381288 Ref-LKTZ1
- IMMULITE®/IMMULITE® 1000 CMV IgG SMN-10381289 Ref-LKCV1
- IMMULITE®/IMMULITE® 1000 Rubella Quantitative IgG
SMN-10381292 Ref-LKRUB1
- IMMULITE®/IMMULITE® 1000 CMV IgM SMN-10381296 Ref-LKCM1
- IMMULITE® 2000 Toxoplasma IgM (μ -Capture)
SMN-10381298 Ref-L2KTZ2
- IMMULITE® 2000 Rubella Quantitative IgG
SMN-10381305 Ref-L2KRUB6
- IMMULITE® 2000 Rubella Quantitative IgG
SMN-10381338 Ref-L2KRUB2
- IMMULITE® 2000 CMV IgG SMN-10381309 Ref-L2KCVG2
- IMMULITE® 2000 CMV IgM SMN-10381320 Ref-L2KCM2

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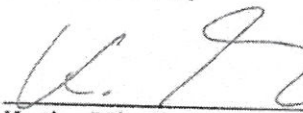
Manufacturer: Siemens Healthcare Diagnostics
Products Ltd.
Glyn Rhonwy, Llanberis,
Gwynedd,
LL55 4EL
United Kingdom

List B Products included:

- IMMULITE® 2000 Toxoplasma Quantitative IgG
SMN-10381323 Ref-L2KTXP2
- IMMULITE® 2000 Rubella IgM SMN-10381327 Ref-L2KRM2
- IMMULITE® Third Generation PSA Control Module
SMN-10385396 Ref-LUPCM
- CMV IgG Controls SMN-10469595 Ref-LCVGCM
- Rubella IgM Controls SMN-10469597 Ref-LRMCM
- Rubella IgG Controls SMN-10469599 Ref-LRUBCM
- Toxoplasma IgG Controls SMN-10469600 Ref-LTXPCM
- PRISCA Software Version 5.2 SMN-10475998
- PRISCA Software Version 5.1 SMN-10730305
- PRISCA 4.0 SMN-11273325
- PRISCA Connect SMN-11273734 Ref-11273733
- PRISCA SHARED DATABASE SMN-11273731 Ref-11273730

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