



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 22 0131 QS/NB

The quality system of manufacturer

Sacace Biotechnologies S.r.l.

via Scalabrini, 44, 22100 Como, Italy

has been certified as meeting the requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex IV excluding (4, 6)

for the following product category(ies):

In Vitro Diagnostic PCR Kits

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

Valid from: 2022-04-13

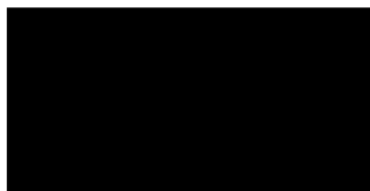
Valid until: 2025-05-26

First Issued: 2022-04-13

Revision: -



Date: 2022-04-13



Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 22 0131 QS/NB

issued for manufacturer:

Sacace Biotechnologies S.r.l.
via Scalabrini, 44, 22100 Como, Italy

Product(s):

Name: HCV Real-TM Quant Dx
Trade name(s): SACACE
Model(s): V1-96/3FRT
Classification: List A
GMDN: 48374

Name: HBV Real-TM Quant Dx
Trade name(s): SACACE
Model(s): V5-96/3FRT
Classification: List A
GMDN: 48307

Name: Toxoplasma gondii Real-TM
Trade name(s): SACACE
Model(s): P1-50FRT
Classification: List B
GMDN: 52428

Name: CMV Real-TM
Trade name(s): SACACE
Model(s): V7-100FRT
Classification: List B
GMDN: 30798

Date: 2022-04-13
Revision: -




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Name: CMV Real-TM Quant
Trade name(s): SACACE
Model(s): V7-100/2FRT
Classification: List B
GMDN: 30798

Name: CMV/EBV/HHV6 Quant Real-TM
Trade name(s): SACACE
Model(s): V48-100FRT
Classification: List B
GMDN: 61348

Name: Chlamydia trachomatis Real-TM
Trade name(s): SACACE
Model(s): B1-100FRT
Classification: List B
GMDN: 47320

Name: Chlamydia trachomatis/Ureaplasma/
M.genitalium Real-TM
Trade name(s): SACACE
Model(s): B46-100FRT
Classification: List B
GMDN: 50409

Date: 2022-04-13
Revision: -




Mgr. Jiří Hes
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issued for manufacturer:

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Name: **Chlamydia trachomatis/Ureaplasma/
M.hominis Real-TM**

Trade name(s): SACACE

Model(s): B43-100FRT

Classification: List B

GMDN: 50409

Name: **Chlamydia trachomatis/Ureaplasma/
M.genitalium/M.hominis Real-TM**

Trade name(s): SACACE

Model(s): B60-100FRT

Classification: List B

GMDN: 50409

Name: **N.gonorrhoeae/C.trachomatis /M.genitalium/
T.vaginalis Real-TM**

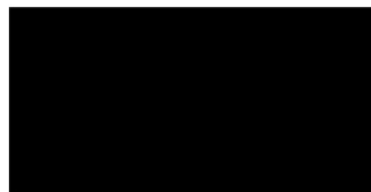
Trade name(s): SACACE

Model(s): B61-100FRT

Classification: List B

GMDN: 50409

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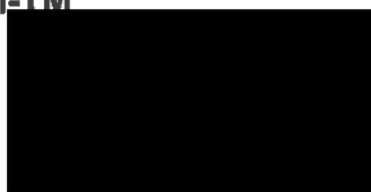
Sacace Biotechnologies S.r.l.
via Scalabrini, 44, 22100 Como, Italy

Name: **N.gonorrhoeae/C.trachomatis/M.genitalium
Real-TM**
Trade name(s): SACACE
Model(s): B67-100FRT
Classification: List B
GMDN: 50409

Name: **HLA B*5701 Real-TM**
Trade name(s): SACACE
Model(s): H53-100FRT
Classification: List B
GMDN: 56403

Name: **T.vaginalis/N.gonorrhoeae/C.trachomatis
Real-TM**
Trade name(s): SACACE
Model(s): B83-100FRT
Classification: List B
GMDN: 50409

Name: **Mycoplasma pneumoniae/Chlamydophila
pneumoniae Real-TM**
Trade name(s): SACACE
Model(s): B42-4-100FRT
Classification: List B
GMDN: 58957
Date: 2022-04-13
Revision: -



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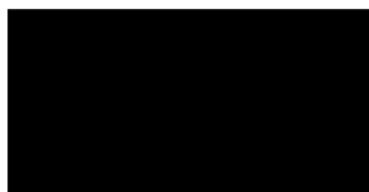
issued for manufacturer:

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Name:	Rubella Real-TM Qual
Trade name(s):	SACACE
Model(s):	V24-50FRT
Classification:	List B
GMDN:	30793



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