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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE No. **4264/5/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.r.l.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Commercializzazione di prodotti del Gruppo: kit diagnostici,
terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi,
provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits,
culture media for microbiology, plastic disposable labware,
test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate,
please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative

Digitally signed by Ceaicovschi Tudor
Date: 2022.11.22 10:14:27 EET
Reason: MoldSign Signature
Location: Moldova

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
www.cisq.com
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CISQ is the Italian Federation of management system Certification Bodies.

0449CM_03_IT

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CERTIFICATO n.
CERTIFICATE No.

4265/5/C

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.r.l.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
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Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
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CISQ is the Italian Federation of management system Certification Bodies.

0860CM_03_IT

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CERTIFICATO n.
CERTIFICATE No.

4265/5/A

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

MEUS S.r.l.

Unità Operative / *Operative Units*
Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia.
Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.
Via dell'Industria 2-16 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Design and production of moulds for plastic labware.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
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Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
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CISQ is the Italian Federation of management system Certification Bodies.

0860CM_03_IT

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

KIMA S.r.l.

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on:	**2022-01-18**
First issued on:	**2007-01-18**
Expires on:	**2025-01-17**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-70247

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

0774CM_03_EN

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CERTIFICATO n.
CERTIFICATE No. **4265/5**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GRUPPO VACUTEST KIMA

Sede / *Head Office*
Via dell'Industria,12 – 35020 Arzergrande (PD) - Italia
Unità Operative / *Operative Units*
MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
MEUS S.r.l. - Via dell'Industria, 2 - 16 – 35020 Arzergrande (PD) - Italia
ROLL S.R.L. - Via Leonardo Da Vinci, 24A – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
KIMA S.R.L. - Via Leonardo da Vinci, 22 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
VACUTEST KIMA S.r.l. - Via dell'Industria,12 – 35020 Arzergrande (PD) – Italia
VACUTEST KIMA S.r.l. via L. Da vInci, 22 Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
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Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
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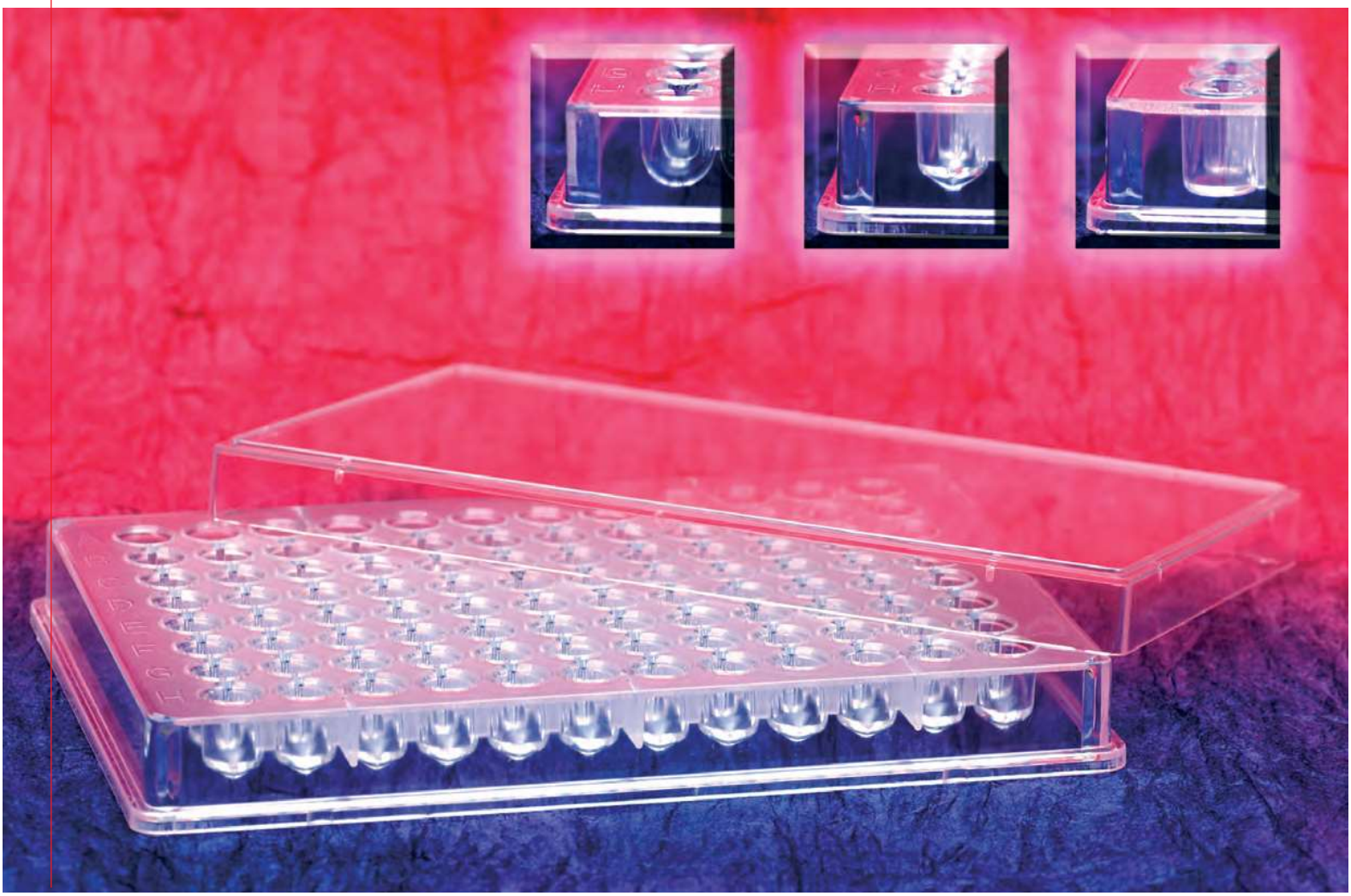
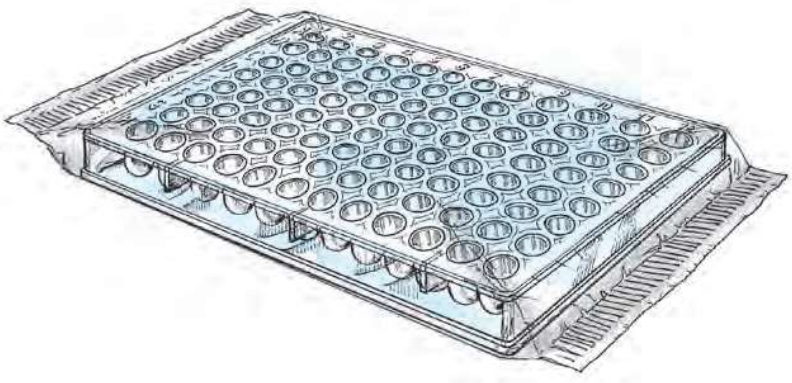
0860CM_03_IT

Piastre per micrometodi

Microtiter Plates





650101
NON STERILE

650111
STERILE

Piastra in polistirolo per micrometodi a 96 cellette con fondo a U. Confezione singola.

Polystyrene microtiter plate with 96 U bottom wells.
Individually wrapped.

CERACARTA S.p.A.

ISO 9001:2008 EN ISO 13485:2012

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipments.
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking system, lottery.
Rfid labels and chain solutions.

Sede (Head office and works) :
Via Secondo Casadei, 14 - 47122 FORLI' – ITALY
Tel : 0039 0543 780055 • Fax : 0039 0543 781404
http : // www.ceracarta.it • e-mail : info@ceracarta.it.
Capitale Sociale : € 1.000.000 int. vers.
Registro Imprese FORLI'-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLI' N. 72646 – N. MECC. FO 006863

Messrs

Medicines and Medical Devices Agency

Forlì, 3rd August 2022

We, CERACARTA SPA V having a registered office at Via Secondo Casadei 14,47122 Forlì(FC)-Italy, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as **Authorized representative** in correspondence with the conditions of LAW No. 102 from 09.06.2017 regarding medical devices.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

Manufacturer: **Ceracarta S.p.A.**

Address: **Via Secondo Casadei, 14 47122 Forlì - ITALY**

DECLARES

that

THE RECORDING "THERMAL" AND/OR "INK" PAPERS IN THE MEDICAL FIELD for "ECG", "EEG","CTG" and papers for laboratory tests (including the model M 1911 A),

identified and classified in the

Technical file ,comply with the directive about medical devices (DIRECTIVE 93/42/CEE as amended by 2007/47/EC).

In addition to this, we precise that:

- according to the Directive 93/42/EEC the listed products are medical devices belonging to class I with function of measure.
- they are subject to the regulations of the Attachment I of the above mentioned directive;
- the evaluation of the device was in accordance with Annex V of that Directive, by the certified body IMQ S.p.A. – CE0051;
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2008

EN ISO 13485:2012

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **"ECG GEL / ECO SUPERGEL ."** ***(BASIC UDI-DI 8059170GC004NN)***,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies;
- the Dispositive in object must be esclusively used together with electro-medical instruments for recording, diagnosis and therapy, which base their functioning upon the measuring of energy flows of electric, magnetic and ultrasound type;
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro
CERACARTA s.p.a.

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015

EN ISO 13485:2016

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **TOP TRACE ECG ELECTRODES *(BASIC UDI-DI 8059170EL001PR)***,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.

In addition:

- the device is tested according to the voluntary Association for the Advancement of Medical Instrumentation (AAMI) standard requirements for electrical performance for disposable ECG electrodes (ANSI/AAMI EC 12:2000) and test results meet or exceed these performance standards.
- the device is tested and it is found to be acceptable for use,according to:

UNI EN ISO 10993-1:"Biological evaluation of medical devices" ;

UNI EN ISO 10993-5 :"Biological evaluation of medical devices :tests for in vitro cytotoxicity";

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015 EN ISO 13485:2016

CERACARTA® S.p.A.

UNI EN ISO 10993-10 :"Biological evaluation of medical devices :tests for irritation and sensitization".

• Ceracarta does not use any latex/PVC materials or ingredients in the manufacturing of our electrodes;

• Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.
Alessandro Bandini

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http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015

EN ISO 13485:2016

CERACARTA S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **"COMPATIBLE PAPER FOR SONY UPP 110 S / HG / HD ROLLS", (BASIC UDI-DI 8059170CA001LN)**,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro
CERACARTA s.p.a.

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Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015 EN ISO 13485:2016

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPC-21L
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Color Printing Pack
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02261

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110S
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02266

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110HG
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02267

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110HD
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-10

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02280

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 9190.CRC3

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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www.imq.it

FEDERAZIONE CISQ

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www.iqnet-certification.com

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ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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FEDERAZIONE CISQ
www.cisq.com
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ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale.
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years.

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CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)
VIA GRAMADORA 12/14 - 47122 FORLI' (FC)
has implemented and maintains a

Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2020 - 09 - 29**
Expires on: ***2023 - 10 - 07***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 112265

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 9124.CRC4

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ

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CISQ is the Italian Federation of management system Certification Bodies.

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www.iqnet-certification.com

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ALLEGATO N. **9124.CRC4-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9124.CRC4
This document is a part of certificate n. 9124.CRC4

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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CISQ is the Italian Federation of management system Certification Bodies.

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ALLEGATO N. **9124.CRC4-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

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Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9124.CRC4
This document is a part of certificate n. 9124.CRC4

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CISQ is the Italian Federation of management system Certification Bodies.

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Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

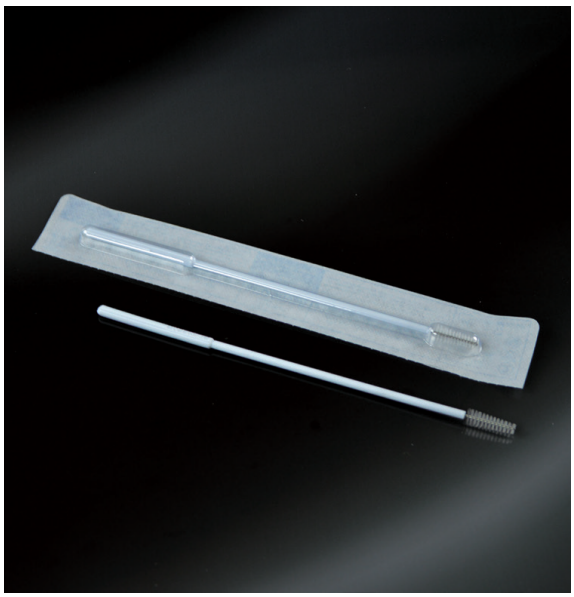
CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
25.11.2021

CODICE ARTICOLO: / *ITEM CODE:* **5631**

DESCRIZIONE / *DESCRIPTION*



CYTO-BRUSH

Spazzolino monouso non sterile per il prelievo endocervicale, per citologia e microbiologia. Consente la raccolta e deposizione sul vetrino di un maggior numero di cellule, senza che le stesse vengano danneggiate.
Dispositivo non citotossico, latex-free

CYTO-BRUSH

Not sterile, disposable brush for endocervical cells collection, in cytology and microbiology. It allows the drawing and laying on slides of a bigger quality of cells, preventing to damage their structure.
Non cytotoxic, Latex-free device

Prodotto con marchio CE conforme al Regolamento (UE) 2017/745 (MDR)

CE Marked device product according to Regulation (EU) 2017/745 (MDR)

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / NOT *STERILE***	*Microbiological status*
Materiale cannula	Polietilene Alta Densità colore bianco *White High Density polyethylene*	*Stick raw material*
Materiale spazzolino	Setole sintetiche anallergiche atraumatiche in poliammide + acciaio inossidabile Synthetic, allergy-free, anti-shock brushes in polyamide + stainless steel	*Brushes raw material*
Lunghezza totale (mm)	185 ± 3	*Total length (mm)*
Diametro cannula (mm)	Ø 3.0 ± 0.3	*Stick diameter (mm)*
Lunghezza spazzolino (mm)	21 ± 1,5	*Brushes length (mm)*
Forma spazzolino	Tronco-conica / *Half-conical shape*	*Brushes shape*
Materiale della busta	Blister in carta medical accoppiata *Blister in medical paper*	*Peel-pouch material*
Validità del prodotto	5 Anni / *Years*	*Shelf life*

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO" – Classe I non sterile - Il CYTO-BRUSH è destinato all'uso ginecologico per il prelievo di cellule in ambito ostetrico e ginecologico per successive indagini diagnostiche. È utilizzato per raccolta di cellule nel tratto endocervicale. Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.
Classificazione Nazionale Dispositivi Medici (CND) > U089002 (Dispositivi per citologia ginecologica)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1899885/R
Basic UDI-DI (GMN – Global Model Number) > 805577609FT23TONGGYNE0177
UDI-DI > 8055776090153

This device is intended as "MEDICAL DEVICE" Class I not sterile – CYTO-BRUSH is intended for gynaecological use for the collection of cells in obstetrics and gynaecology for subsequent diagnostic investigations. It is used for cell collection in the endocervical tract. For professional use only.
***National classification of medical devices (CND - For Italian law) >** U089002 (Gynaecological cytology devices)*
***Basic UDI-DI (GMN – Global Model Number) >** 805577609FT23TONGGYNE0177*
***UDI-DI >** 8055776090153*

MANIPOLAZIONE / *HANDLING*

Per la manipolazione, prima dell'utilizzo lavare le mani con sapone disinfettante e utilizzare idonei guanti. Non sono previste altre condizioni di manipolazione particolari

For handling, before the use, wash your hands with disinfectant soap and use appropriate gloves. There are no other special handling conditions

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Effettuare il prelievo nel fornice vaginale quindi inserire delicatamente lo scovolino del CYTO-BRUSH nell'endocervice facendo in modo che le setole rimangano visibili. Ruotare di 360° una sola volta indi rimuovere ed estrarre. Attenzione: non usare il CYTO-BRUSH per prelievi endometriali. Se usato su pazienti gravide agire delicatamente. Destinato esclusivamente ad uso professionale. Il Dispositivo è monouso e non va riutilizzato: pericolo di infezioni e perdita di funzionalità. Conservare in luogo fresco e asciutto, proteggere dall'umidità. Smaltire dopo l'uso in accordo alle normative vigenti.

First make the sampling in the vaginal fornix then gently insert the brush side of CYTO-BRUSH in the endocervix leaving the bristles visible. Rotate one full turn and then remove. Caution: do not use CYTO-BRUSH for endometrial sampling. Be gentle with pregnant patients. For professional use only. Disposable - do not reuse: risk of infection and loss of functionality. Store in a cool and dry place, protect from dampness. Dispose after use according to the regulations in force.

DETERIORAMENTO DEL PRODOTTO / *PRODUCT DAMAGES*

Non utilizzare le unità se presentano tracce di danneggiamento o contaminazione. Non usarle se già scadute.

Do not use the units in case of damages or contamination. Do not use after expiry date.

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	500	Confezione interna (pz): *Internal packing (pcs):*	100	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	29 x 17,5 x 17	Peso (Kg): *Weight (Kg):*	2,5	Volume (m^3): *Volume (m^3):*	0,009

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS* (UNI EN CEI ISO 15223-1)

CE	Marchio CE *CE Mark*	MD	Dispositivo Medico *Medical Device*	NON STERILE	Non sterile *Non-sterile*
	Data di produzione *Date of manufacture*		Data di scadenza *Use-by date*	LOT	Lotto *Batch code*
REF	Codice articolo *Catalogue number*		Fabbricante *Manufacturer*		Monouso *Do not re-use*
	Non esporre ai raggi del sole *Keep away from sunlight*		Proteggere dall'umidità *Keep dry*		

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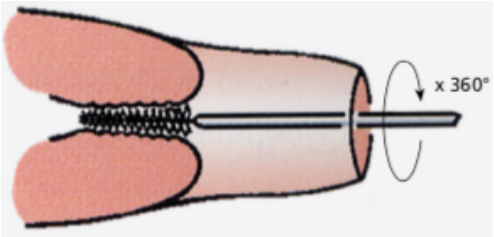
ISTRUZIONI PER L'USO / *INSTRUCTIONS OF USE*

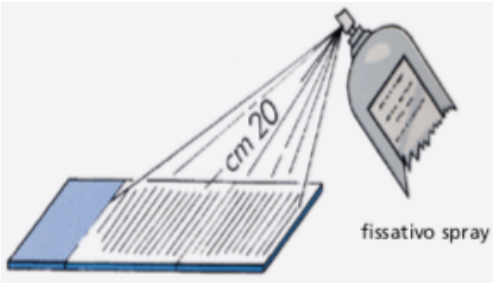
1. Effettuare il prelievo inserendo delicatamente il dispositivo nell'endocervice, per tutta la lunghezza dello scovolo.
2. Ruotare per 360° le setole con una sola manovra e quindi estrarre.
3. Depositare il materiale prelevato su un vetrino, ruotando e premendo delicatamente lo scovolo sul vetrino. Effettuare una pressione leggera per mantenere l'integrità delle cellule ed evitare processi di degenerazione. Il materiale strisciato deve essere sottile perché la presenza di strati sovrapposti impedisce un'adeguata lettura del preparato.
4. Fissaggio: fissare immediatamente il preparato per evitare fenomeni di degenerazione cellulare conseguenti all'essiccazione: anche una breve attesa può danneggiare le cellule.
5. Nel caso si utilizzi un fissativo sotto forma di spray, il dispositivo deve essere tenuto a distanza di 15 /20 cm dal vetrino: infatti se effettuata a minor distanza, la potenza dell'erogazione sposterà le cellule alla periferia e indurrà la formazione di bolle d'aria al centro del vetrino stesso.
6. Lasciare il vetrino ad asciugare in posizione orizzontale.
7. Smaltire il CYTO-BRUSH secondo le normative vigenti.



ATTENZIONE: in casi di gravidanza usare delicatamente. Non usare per prelievo endometriale.

Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.

1. *Proceed to drawing by delicately introducing the device into the endocervices, for the length of brushes;*
2. *Turn brushes at 360° by one single turn and then extract the device;*
3. *Lay drawn sample on a slide by turning brushes and slightly pressing them on it. Make a slight pressure to maintain the integrity of the cells and prevent degenerative processes. The material crawled must be thin because the presence of superimposed layers prevents an adequate reading of the preparation.*
4. *Fixing: fix the prepared immediately to prevent spontaneous cell degeneration consequent drying: even a short delay may cause damage to the cells.*
5. *If you are using a fixative spray form, the device must be kept at a distance of 15/20 cm from the slide: in fact, if carried out in the shortest distance, the power delivery of the cells moves to the periphery and induce the formation of air bubbles in the centre of the slide.*
6. *Allow the slide to dry in a horizontal position.*
7. *Dispose the CYTO-BRUSH according to current regulations.*



WARNING: *the use of the device in case of pregnancy must be extremely delicate. Do not use for endometrial drawing.*

For professional use only.

Thermo SCIENTIFIC

PRODUCT INFORMATION

Thermo Scientific DreamTaq Hot Start DNA Polymerase

Pub. No. MAN0015972
Rev. Date 29 July 2016 (Rev. A.00)

Lot: __ Expiry Date: __

Ordering Information

Catalog No.	DreamTaq Hot Start DNA Polymerase, 5 U/µL	10X DreamTaq Buffer*
EP1701	200 U	1.25 mL
EP1702	500 U	2 × 1.25 mL
EP1703	2500 U	10 × 1.25 mL
EP1704	4 × 2500 U	40 × 1.25 mL

* includes 20 mM $MgCl_2$

Store at –20°C

www.thermofisher.com

For Research Use Only. Not for use in diagnostic procedures.

DESCRIPTION

Thermo Scientific™ DreamTaq™ Hot Start DNA Polymerase is an enhanced hot start *Taq* DNA polymerase optimized for most PCR applications. It ensures higher sensitivity, specificity, and yields compared to conventional hot start *Taq* DNA polymerase. It is capable of amplifying long amplicons such as 6 kb genomic DNA and 20 kb λ DNA.

DreamTaq Hot Start DNA Polymerase combines *Taq* DNA polymerase and a specific antibody that inhibits the DNA polymerase activity at ambient temperatures, thus preventing the amplification of non-specific products. At polymerization temperatures, the antibody molecule is released, rendering the polymerase fully active.

DreamTaq Hot Start DNA Polymerase uses the same reaction set-up and cycling conditions as conventional *Taq* DNA polymerases, but the antibody-based hot start allows the reactions to be set up at room temperature. Because the enzyme is supplied with the optimized DreamTaq buffer, which includes 20 mM $MgCl_2$, extensive optimization of reaction conditions is not required.

DreamTaq Hot Start DNA Polymerase generates PCR products with 3'-dA overhangs. The enzyme tolerates dUTP and can incorporate modified nucleotides.

FEATURES

- High specificity due to antibody based hot start.
- Robust amplification with minimal optimization.
- High yields of PCR products.
- Higher sensitivity compared to conventional hot start *Taq* DNA polymerases.
- Amplification of long targets up to 6 kb from genomic DNA and up to 20 kb from viral DNA.
- Generates 3'-dA overhangs.
- Incorporates dUTP and modified nucleotides.

APPLICATIONS

- Routine PCR amplification of DNA fragments up to 6 kb from genomic DNA and up to 20 kb from viral DNA.
- RT-PCR.
- Genotyping.
- Generation of PCR products for TA cloning.

CONCENTRATION

5 U/µL

DEFINITION OF ACTIVITY UNIT

One unit of the enzyme catalyzes the incorporation of 10 nmol of deoxyribonucleotides into a polynucleotide fraction in 30 minutes at 74°C.

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10X DREAMTAQ BUFFER

DreamTaq Buffer is a proprietary formulation, which contains KCl and $(NH_4)_2SO_4$ at a ratio optimized for robust performance of DreamTaq Hot Start DNA Polymerase in PCR. DreamTaq Buffer also includes $MgCl_2$ at a concentration of 20 mM.

INHIBITION AND INACTIVATION

- Inhibitors: Ionic detergents (deoxycholate, sarkosyl, and SDS) at concentrations higher than 0.06, 0.02, and 0.01%, respectively.
- Inactivated by phenol/chloroform extraction.

PROTOCOL

To set up parallel reactions and to minimize the possibility of pipetting errors, prepare a PCR master mix by mixing water, buffer, dNTPs, primers, and DreamTaq Hot Start DNA Polymerase. Prepare sufficient master mix for the number of reactions plus one extra. Aliquot the master mix into individual PCR tubes, then add template DNA.

1. Gently vortex and briefly centrifuge all solutions after thawing.
2. For each 50-µL reaction, add the following components into a thin-walled PCR tube:

10X DreamTaq Buffer*	5 µL
dNTP Mix, 2 mM each (#R0241)	5 µL (0.2 mM of each)
Forward primer	0.1–1.0 µM
Reverse primer	0.1–1.0 µM
Template DNA	10 pg–1 µg
DreamTaq Hot Start DNA Polymerase	1.25 U
Water, nuclease-free (#R0581)	to 50 µL
Total volume	50 µL

*10X DreamTaq Buffer contains 20 mM $MgCl_2$, which is optimal for most applications. If further optimization is required, additional $MgCl_2$ can be added to the master mix. The volume of water should be reduced accordingly.

Volumes of 25 mM $MgCl_2$ (#R0971), required for specific final $MgCl_2$ concentration:

Final concentration of $MgCl_2$	2 mM	2.5 mM	3 mM	4 mM
Volume of 25 mM $MgCl_2$ to be added for 50-µL reaction	0 µL	1 µL	2 µL	4 µL

3. Gently vortex the samples and briefly centrifuge.
4. When using a thermal cycler that does not contain a heated lid, overlay the reaction mixture with 25 µL of mineral oil.
5. Place the reactions in a thermal cycler. Perform PCR using the recommended thermal cycling conditions outlined below:

Step	Temperature, °C	Time	Number of cycles
Initial denaturation	95	1–3 min	1
Denaturation	95	30 s	25–40
Annealing	Tm	30 s	
Extension*	72	1 min	
Final Extension	72	5–15 min	1

* The recommended extension step is 1 minute for PCR products up to 2 kb. For longer products, the extension time should be prolonged by 1 minute/kb.

GUIDELINES FOR PREVENTING CONTAMINATION OF PCR REACTION

During PCR more than 10 million copies of template DNA are generated. Therefore, care must be taken to avoid contamination with other templates and amplicons that may be present in the laboratory environment. Follow the general recommendations below to lower the risk of contamination.

- Prepare your DNA sample, set up the PCR mixture, perform thermal cycling and analyze PCR products in separate areas.
- Set up PCR mixtures in a laminar flow cabinet equipped with an UV lamp.
- Wear fresh gloves for DNA purification and reaction set up.
- Use reagent containers dedicated for PCR. Use positive displacement pipettes, or use pipette tips with aerosol filters to prepare DNA samples and perform PCR set up.
- Use PCR-certified reagents, including high quality water (e.g., Water, nuclease-free, #R0581).
- Always perform "no template control" (NTC) reactions to check for contamination.

DreamTaq Hot Start DNA Polymerase incorporates dUTP; therefore, you can control carry-over contamination using Uracil-DNA Glycosylase (#EN0361).

GUIDELINES FOR PRIMER DESIGN

Use special design software or follow the general recommendations for PCR primer design as outlined below to design optimal primers:

- Use PCR primers that are 15–30 nucleotides long.
- Optimal GC content of the primer is 40 –60%. Ideally, C and G nucleotides should be distributed uniformly along the primer.
- Avoid placing more than three G or C nucleotides at the 3'-end to lower the risk of non-specific priming.
- If possible, the primer should terminate with a G or C at the 3'-end.

(continued on reverse page)

- Avoid self-complementary primer regions, and complementarities between the primers and direct primer repeats to prevent hairpin formation and primer dimerization.
- Check for possible sites of undesired complementarity between primers and template DNA.
- When designing degenerate primers, place at least 3 conserved nucleotides at the 3'-end.
- Differences in melting temperatures (Tm) between the two primers should not exceed 5°C.

ESTIMATION OF PRIMER MELTING TEMPERATURE

For primers containing less than 25 nucleotides, the approximate melting temperature (Tm) can be calculated using the following equation:

$$Tm = 4 (G + C) + 2 (A + T),$$

where G, C, A, T represent the number of respective nucleotides in the primer.

If the primer contains more than 25 nucleotides, we recommend using specialized computer programs to account for interactions of adjacent bases, effect of salt concentration, etc.

COMPONENTS OF THE REACTION MIXTURE

Template DNA

Optimal amount of template DNA for a 50-µL reaction volume is 1 pg–1 ng for both plasmid and phage DNA, and 100 pg–1 µg for genomic DNA. Higher amounts of template increase the risk of non-specific PCR products. Lower amounts of template reduce the accuracy of the amplification.

All routine DNA purification methods are suitable for template preparation; e.g., Thermo Scientific™ GeneJET™ Genomic DNA Purification Kit (#K0721) or GeneJET Plasmid Miniprep Kit (#K0502). Trace amounts of certain agents used for DNA purification, such as phenol, EDTA, and proteinase K, can inhibit DNA polymerases. Ethanol precipitation and repeated washes of the DNA pellet with 70% ethanol normally removes trace contaminants from DNA samples.

$MgCl_2$ concentration

DreamTaq Hot Start DNA Polymerase is provided with an optimized 10X DreamTaq Buffer, which includes $MgCl_2$ at a concentration of 20 mM. A final $MgCl_2$ concentration of 2 mM is generally ideal for PCR. $MgCl_2$ concentration can be further increased up to 4 mM by the addition of 25 mM $MgCl_2$ (#R0971).

If the DNA samples contain EDTA or other metal chelators, Mg^{2+} ion concentration in the PCR mixture should be increased accordingly (1 molecule of EDTA binds 1 Mg^{2+}).

dNTPs

The recommended final concentration of each dNTP is 0.2 mM. In certain PCR applications, higher dNTP concentrations may be necessary. It is essential to have equal concentrations of all four nucleotides (dATP, dCTP, dGTP and dTTP) in the reaction mixture.

To obtain a 0.2 mM concentration of each dNTP in the PCR mixture, refer to the table below.

Volume of PCR mixture	dNTP Mix, 2 mM each (#R0241)	dNTP Mix, 10 mM each (#R0191)	dNTP Mix, 25 mM each (#R1121)
50 µL	5 µL	1 µL	0.4 µL
25 µL	2.5 µL	0.5 µL	0.2 µL
20 µL	2 µL	0.4 µL	0.16 µL

Use 200 µM of each dNTP. dUTP or dITP can be added up to 200 µM. For longer amplicons, a lower dUTP concentration (20–100 µM) may be required for high yields.

Primers

The recommended concentration range of the PCR primers is 0.1–1 µM. Excessive primer concentrations increase the probability of mispriming and generation of non-specific PCR products.

For degenerate primers and primers used for long PCR, we recommend higher primer concentrations in the range of 0.3–1 µM.

CYCLING PARAMETERS

Initial DNA denaturation and enzyme activation

DreamTaq Hot Start DNA polymerase is inactive at room temperature during the reaction set up and is activated during the 1–3 minute initial denaturation/enzyme activation step.

It is essential to completely denature the template DNA at the beginning of the PCR run to ensure efficient utilization of the template during the first amplification cycle. If the GC content of the template is 60% or less, an initial 1–3 minute denaturation at 95°C is sufficient. For GC-rich templates this step can be prolonged.

Denaturation

A DNA denaturation time of 30 seconds per cycle at 95°C is normally sufficient. For GC-rich DNA templates, this step can be prolonged to 3–4 minutes. DNA denaturation can also be enhanced by the addition of 5–10% glycerol, 5% DMSO, 1% formamide, or 1–1.5 M betaine. The melting temperature of the primer-template complex decreases significantly in the presence of these reagents. Therefore, the annealing temperature has to be adjusted accordingly.

Note that higher than 10% DMSO or 5% formamide in the reaction mix inhibit DNA polymerases. Therefore, it may be necessary to increase the amount of the enzyme in the reaction if these additives are used.

Primer annealing

The annealing temperature should be equal to the melting temperature (Tm) of the primers. Annealing for 30 seconds is normally sufficient. If non-specific PCR products appear, the annealing temperature should be optimized stepwise in 1-2°C increments. When additives that change the melting temperature of the primer-template complex are used (glycerol, DMSO, formamide and betaine), the annealing temperature must also be adjusted.

Extension

The optimal extension temperature for DreamTaq Hot Start DNA Polymerase is 70–75°C. The recommended extension step is 1 minute at 72°C for PCR products up to 2 kb. For longer products, the extension time should be increased by 1 minute/kb. For amplification of templates >6 kb, we recommend reducing the extension temperature to 68°C.

Number of cycles

The number of cycles may vary depending on the amount of template DNA in the PCR mixture and the expected PCR product yield.

If less than 10 copies of the template is present in the reaction, about 40 cycles are required. For higher template amounts, 25–35 cycles are sufficient.

Final extension

After the last cycle, we recommend incubating the PCR mixture at 72°C for an additional 5–15 minutes to fill in any possible incomplete reaction products. If the PCR product will be cloned into TA vectors such as the Thermo Scientific™ InsTAclone™ PCR Cloning Kit (#K1213), the final extension step may be prolonged to 15 minutes to ensure the complete 3'-dA tailing of the PCR product. If the PCR product will be used for cloning using Thermo Scientific™ CloneJET™ PCR Cloning Kit (#K1231), the final extension step can be omitted.

TROUBLESHOOTING

For troubleshooting, visit **www.thermofisher.com.**

CERTIFICATE OF ANALYSIS

Endodeoxyribonuclease Assay

No detectable conversion of supercoiled plasmid DNA to a nicked form was observed.

Residual Activity Assay

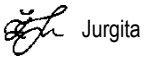
No detectable extension of labeled double stranded oligonucleotide with 5'-overhangs after incubation in the presence of dNTPs.

E. coli DNA Assay

No detectable E.coli DNA was observed.

Functional Assay

Performance in PCR is tested by the amplification of a 594 bp and 7.5 kb fragments of human genomic DNA.

Quality authorized by:  Jurgita Zilinskiene

PRODUCT USE LIMITATION

This product is developed, designed and sold exclusively for research purposes and in vitro use only. The product was not tested for use in diagnostics or for drug development, nor is it suitable for administration to humans or animals.

For Research Use Only. Not for use in diagnostic procedures.

Refer to **www.thermofisher.com/support** for the Safety Data Sheets.

DreamTaq Hot Start DNA Polymerase

The hot-start polymerase for everyday research

New Thermo Scientific™ DreamTaq™ Hot Start DNA Polymerase offers a great balance between performance and value. Designed for consistently robust and reliable amplification, DreamTaq Hot Start DNA Polymerase can help you more easily get the results you're looking for, with virtually any template, application, or target.

Why use hot-start PCR?

- Prevents amplification of nonspecific products
- Amplifies low-abundance targets
- Provides convenient room-temperature setup

Why use DreamTaq Hot Start DNA Polymerase?

DreamTaq Hot Start DNA Polymerase is the hot-start version of our enhanced Thermo Scientific™ DreamTaq™ DNA Polymerase. Like our standard DreamTaq DNA Polymerase, this hot-start polymerase offers higher yields and longer amplicons than conventional *Taq*-based products. In addition, due to the hot-start modification, DreamTaq Hot Start DNA Polymerase has been engineered to provide increased sensitivity and specificity.

Features:

- Minimized optimization of primer annealing temperatures
- Optimized DreamTaq™ buffer, which includes 20 mM $MgCl_2$
- Ability to use same cycling conditions as used with conventional *Taq* polymerase
- Wide range of amplicon lengths
- 2X master mix formats
- Direct loading options
- Compatibility with most PCR applications

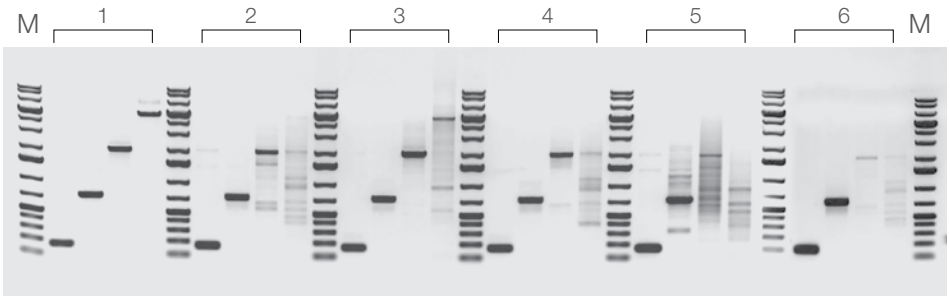


Figure 1. Robust amplification of human genomic DNA. DreamTaq Hot Start DNA Polymerase produces more product, cleaner bands, and longer amplicons than hot-start DNA polymerases from other suppliers. Amplification products (160 bp, 727 bp, 2 kb, or 5 kb) from human genomic DNA are shown in the figure above.
M: GeneRuler 1 kb Plus DNA Ladder. 1. DreamTaq Hot Start DNA Polymerase; 2. Promega GoTaq G2 Hot Start Polymerase; 3. NEB One*Taq* Hot Start DNA Polymerase; 4. TaKaRa *Taq* DNA Polymerase Hot Start Version; 5. Kapa Biosystems KAPA2G Robust HotStart PCR Kit; 6. Bioline MyTaq HS DNA Polymerase.

ThermoFisher SCIENTIFIC

thermo scientific

Technical details

- Amplifies from as little as 3 pg human genomic DNA
- Routinely amplifies up to 6 kb genomic DNA and 20 kb lambda DNA
- Generates 3´-dA overhangs
- Incorporates dUTP and modified nucleotides

Usage and applications

Choose DreamTaq Hot Start DNA Polymerase for the amplification of DNA from plasmid, viral, or complex genomic templates. Common applications include:

- Colony PCR
- Genotyping
- RT-PCR
- Generation of PCR products for TA cloning

Why use green?

The Thermo Scientific™ DreamTaq™ Green Buffer (10X) supports direct gel loading of PCR products. The two tracking dyes and a density reagent in the green buffer do not interfere with PCR performance and are compatible with downstream applications including DNA sequencing, ligation, and restriction digestion.

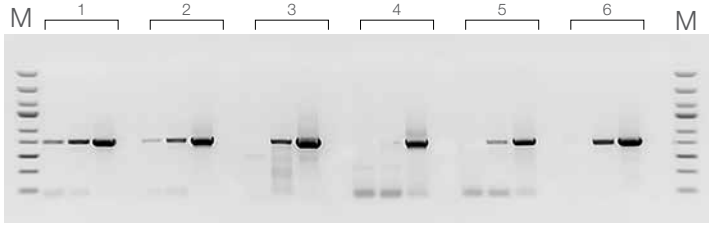


Figure 2. High sensitivity. DreamTaq Hot Start DNA Polymerase amplifies from lower template amounts than hot-start DNA polymerases from other suppliers. Each set of PCR reactions contained either 3 pg, 30 pg, or 3 ng of human genomic DNA.
M: GeneRuler Express DNA Ladder. 1. DreamTaq Hot Start DNA Polymerase; 2. TaKaRa *Taq* DNA Polymerase Hot Start Version; 3. Kapa Biosystems KAPA2G Robust HotStart PCR Kit; 4. Bioline MyTaq HS DNA Polymerase; 5. NEB One*Taq* Hot Start DNA Polymerase; 6. Promega GoTaq G2 Hot Start Polymerase.

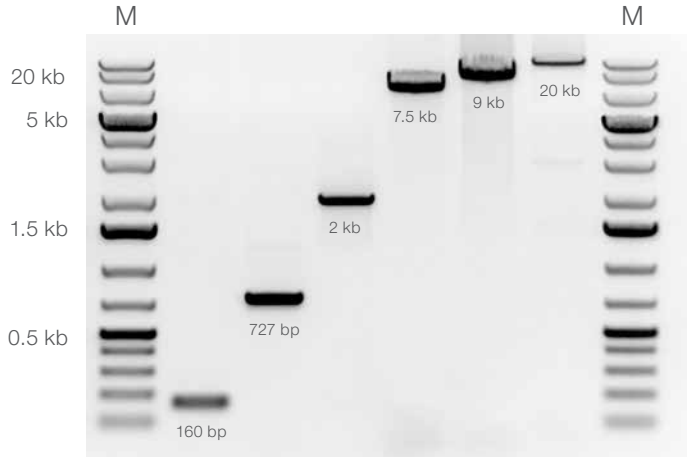


Figure 3. Consistent and reliable amplification. DreamTaq Hot Start DNA Polymerase amplifies human genomic DNA with high specificity up to 9 kb amplicons. Even longer 20 kb amplicons can be amplified with lambda DNA templates.
M: Thermo Scientific™ GeneRuler™ 1 kb Plus DNA Ladder.

Ordering information

Product	Quantity	Cat. No.
DreamTaq Hot Start DNA Polymerase	200 U	EP1701
	500 U	EP1702
	2,500 U	EP1703
	4 x 2,500 U	EP1704
DreamTaq Hot Start PCR Master Mix	200 reactions	K9011
	1,000 reactions	K9012

Product	Quantity	Cat. No.
DreamTaq Hot Start Green DNA Polymerase	200 U	EP1711
	500 U	EP1712
	2,500 U	EP1713
	4 x 2,500 U	EP1714
DreamTaq Hot Start Green PCR Master Mix	200 reactions	K9021
	1,000 reactions	K9022

Find out more at **thermofisher.com/dreamtaq**

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TaqMan multiplex real-time PCR

Get more data out of your sample

- A complete multiplex real-time PCR (qPCR) solution for gene expression and genotyping applications
- Applied Biosystems™ ABY™ and JUN™ dyes, QSY™ quencher, and a multiplex master mix for optimal amplification performance
- Up to 4-plex reactions—as sensitive as singleplex reactions, decreases the starting material required, and minimizes optimization processes

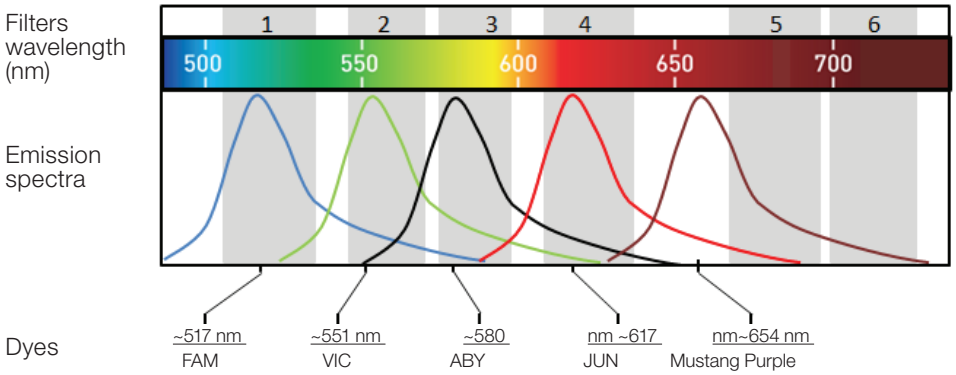

Figure 1. Fluorescence emission spectra of FAM, VIC, ABY, and JUN dyes used for multiplex real-time PCR. Grey zones represent the filters available on Applied Biosystems™ real-time PCR systems: 1 through 6 for the QuantStudio™ 7 or 12K Flex Real-Time PCR Systems; 1 through 5 for the QuantStudio™ 6 Flex Real-Time PCR System, ViiA™ 7 Real-Time PCR System, and 7500 or 7500 Fast Real-Time PCR System. MP = Mustang Purple™ dye.

Obtaining the maximum amount of genetic information from an important but small amount of sample can be challenging. This is particularly true with formalin-fixed, paraffin-embedded (FFPE) samples or tumor biopsies that are used for translational research studies. Singleplex qPCR is frequently used for these clinical research samples, but this typically has a higher cost per sample than running in multiplex format. The additional time and materials required to set up multiple single-assay reactions could also significantly increase the cost of a complex project.

Multiplex qPCR, a strategy where more than one target in a sample is amplified and quantified in a single tube, can decrease the quantity of sample material and reagents required. A complete solution for multiplex qPCR is presented here, with components designed to work together for better data quality and less time for optimization. The solution consists of the following:

- Applied Biosystems™ TaqMan® probes using QSY quencher, providing maximal PCR efficiency in a multiplex format. These probes can be ordered with Applied Biosystems™ FAM™ and VIC™ dyes and also with the ABY and JUN dyes, allowing amplification of up to 4 targets in a single reaction. These reporter dyes are optimized to work together with minimal spectral overlap for improved performance (Figure 1). In addition, the QSY quencher is fully compatible with probes that have minor-groove binder (MGB) quenchers.
- The Applied Biosystems™ TaqMan® Multiplex Master Mix was developed to allow amplification of 4 targets simultaneously, without competition between targets. This master mix contains the Applied Biosystems™ Mustang Purple™ dye, a passive reference used for normalization instead of the Applied Biosystems™ ROX™ dye, allowing for measurement of JUN dye in the channel previously used to measure ROX dye.

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- Off-the-shelf, predesigned assays—an RNase P assay using an ABY-QSY probe and a GAPDH assay using a JUN-QSY probe. Both assays are available in limited and nonlimited primer concentrations.
- Calibration plates for ABY, JUN, and Mustang Purple dyes, available in 96-well, 96-well Fast, and 384-well formats.
- Additional services provided through our custom services program—save time and let our Applied Biosystems™ TaqMan® Assay experts design your multiplex assays.

This multiplex solution is compatible with the Applied Biosystems™ QuantStudio™ 6, 7, and 12K Flex Real-Time PCR Systems, as well as the Applied Biosystems™ ViiA™ 7 Real-Time PCR System and the Applied Biosystems™ 7500 and 7500 Fast Real-Time PCR Systems.

Multiplexing without compromise

The multiplex format enables cost savings and preservation of limited sample, but it's important to obtain the same sensitivity as in the singleplex format. Figure 2 demonstrates comparable results between reactions performed in individual tubes or in 4-plex reactions for a gene quantification experiment.

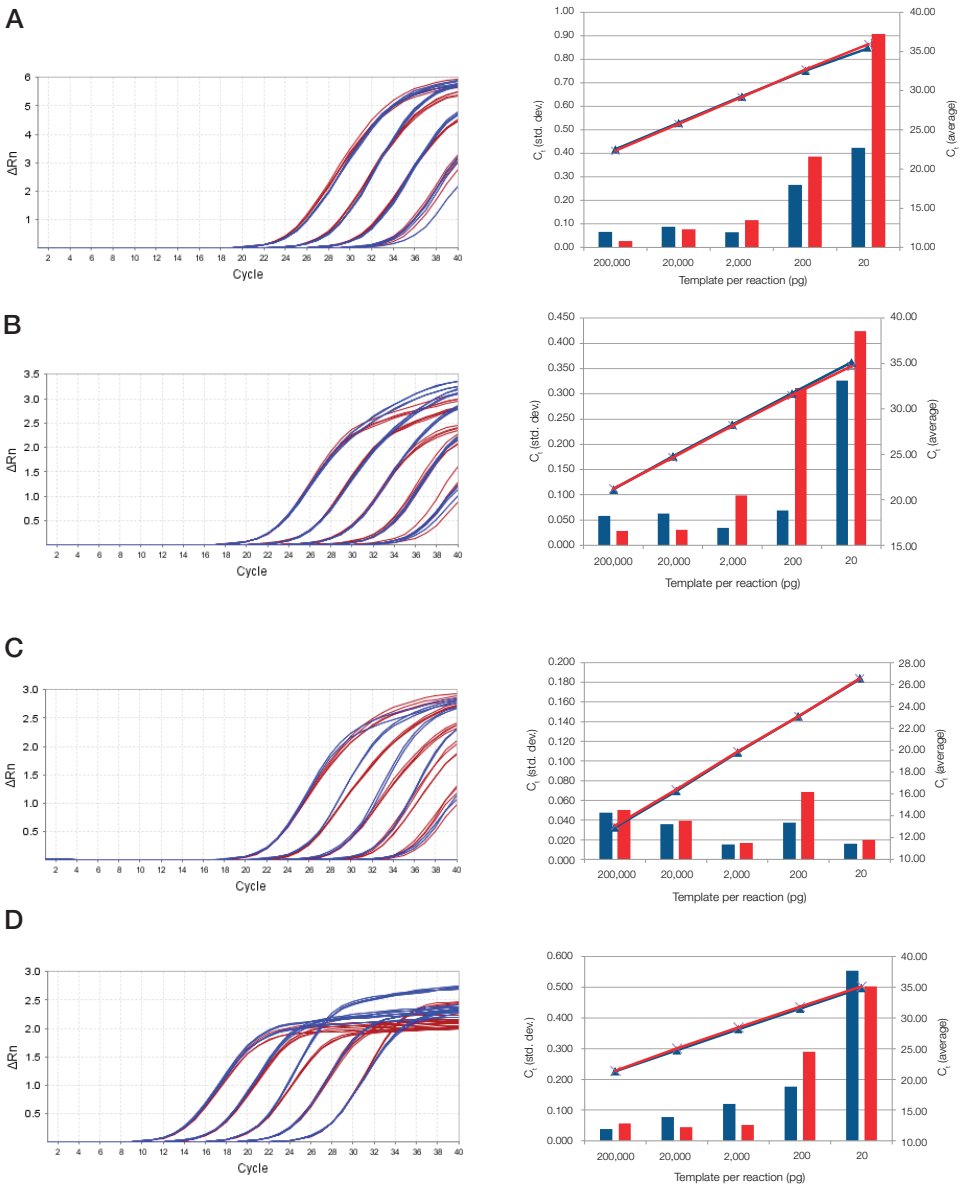

Figure 2. Comparison of singleplex and multiplex gene expression assays. (A) EGFR assay, FAM dye; **(B)** BRCA1 assay, VIC dye; **(C)** ESR1 assay, JUN dye; **(D)** RNase P assay, ABY dye. Amplification was performed on the QuantStudio 7 Real-Time PCR System using TaqMan Multiplex Master Mix. The figure shows amplification plots (left) and linear curves (right) for 4 assays amplified in singleplex (blue) and 4-plex reactions (red) in a dilution series from 20,000 pg to 2 pg of reference colon cDNA per 10 µL reaction. Average C_t value (lines) and average standard deviation (bars) for the dilution series are represented in their respective graphs and show the concordance between singleplex and 4-plex reactions. PCR efficiencies are: 96.09% for EGFR singleplex and 96.39% for EGFR 4-plex; 93.56% for BRCA1 singleplex and 94.93% for BRCA1 4-plex; 97.13% for ESR1 singleplex and 95.81% for ESR1 4-plex; 96.91% for RNase P singleplex and 98.1% for RNase P 4-plex.

Improved probe performance

Introduction of ABY and JUN reporter dyes and Mustang Purple passive reference dye allows for optimal 4-color multiplex assays when used with our FAM and VIC reporter dyes. Please note that ABY and JUN reporter dyes are available only with QSY quencher, while FAM and VIC dyes are available with either MGB or QSY quencher. A comparison with a set of dyes from another supplier shows that our combination of dyes provides an earlier C_t for the majority of assays (Figure 3).

Optimized multiplex master mix

In multiplex PCR, it's important to have a robust master mix that allows for amplification of each target in a highly competitive environment. Our new master mix composition was developed to provide optimal multiplex performance for each target in the reaction. A comparison of our master mix and a master mix from another supplier in a 4-plex reaction shows an earlier C_t for 3 of the targets amplified with our new master mix and a lower standard deviation for most of the dilution points, demonstrating the excellent performance of our solution (Figure 4).

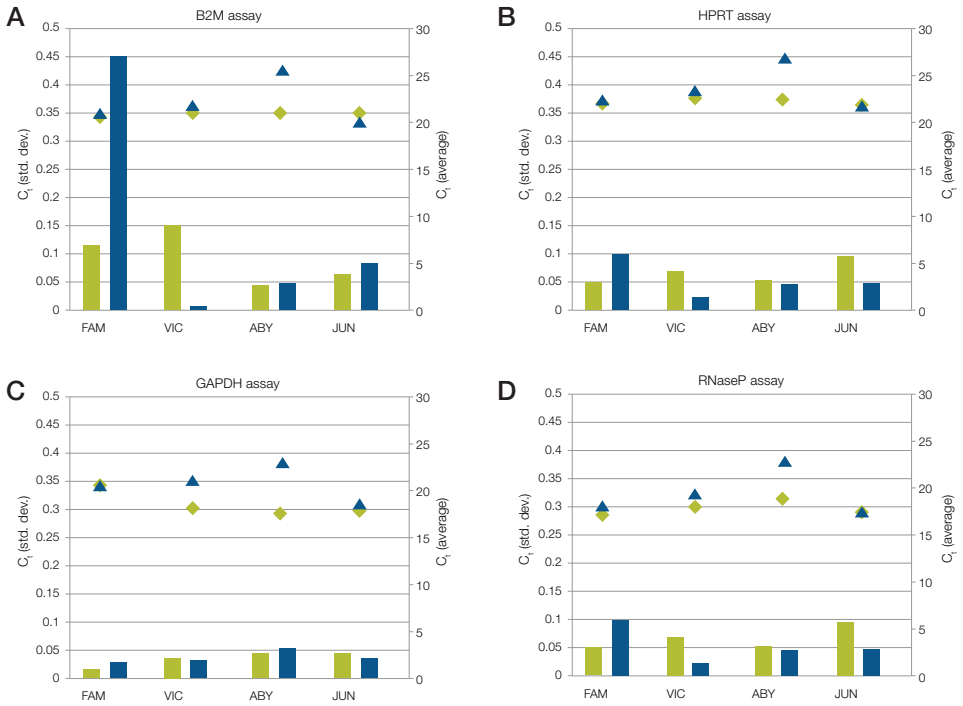

Figure 3. Comparison of our new dye combination with a dye combination from another supplier. Probes for **(A)** B2M, **(B)** HPRT, **(C)** GAPDH, and **(D)** RNase P gene expression assays were synthesized with FAM, VIC, ABY, and JUN dyes with QSY quencher (green bars and diamonds) and with another commercially available dye combination (blue bars and triangles). All possible gene-dye combinations were tested. Reactions were prepared with TaqMan Multiplex Master Mix using 900 nM of primer, 250 nM of probe, and 10 ng of cDNA. Amplification was performed on the QuantStudio 7 Real-Time PCR System using TaqMan Multiplex Master Mix. Bars represent average standard deviation. Triangles and diamonds represent average C_t values.

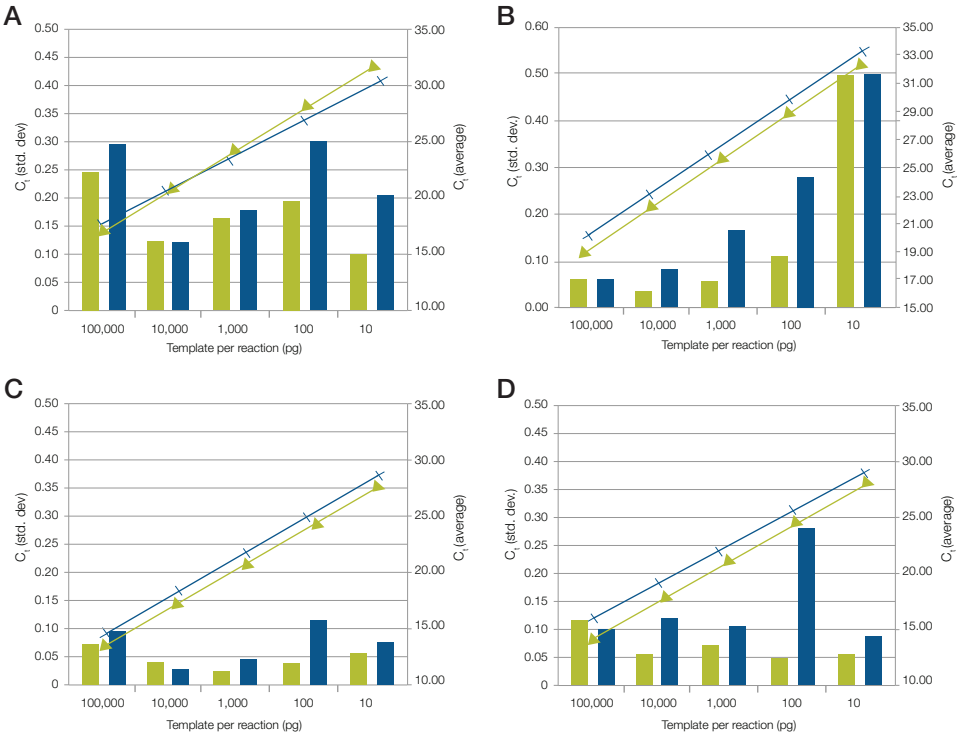

Figure 4. Comparison of TaqMan Multiplex Master Mix with another commercially available master mix. (A) B2M assay, FAM dye; **(B)** RNase P assay, VIC dye; **(C)** GAPDH assay, ABY dye; **(D)** HPRT assay, JUN dye. All assays used QSY quencher. The graph shows average standard deviation (bars) and average C_t values (cross and triangle) for 4-plex reactions using a dilution series from 100 ng to 10 pg of cDNA per 10 µL reaction. All amplifications were performed on the ViiA 7 Real-Time PCR System using the cycling conditions recommended for each master mix. Green represents TaqMan Multiplex Master Mix, and blue represents 4-plex reactions with another commercially available master mix.

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Optimized to minimize time-to-results

Developing a multiplex PCR assay requires time to correctly design the assay and optimize the reaction. Using our complete solution, for which all components were developed to work together, helps increase your chances of success and limits your development time. A new multiplex PCR user guide was developed to guide you through the development and optimization process [1], and our custom services will allow you to delegate assay design to our experienced team to minimize your efforts.

References

1. Multiplex PCR User Guide. Available at thermofisher.com/multiplexqpcr
2. TaqMan multiplex qPCR: Accurate, sensitive, and as efficient as traditional singleplex qPCR. Application note available at lifetechnologies.com/multiplexqpcr

Ordering information

Product	Cat. No.
TaqMan QSY probes	
TaqMan QSY Probe, 6,000 pmol	4482777
TaqMan QSY Probe, 20,000 pmol	4482778
TaqMan QSY Probe, 50,000 pmol	4482779
Control kits	
TaqMan GAPDH Assay, JUN-QSY 20X	4485712
TaqMan GAPDH Assay, JUN-QSY PL 20X	4485713
TaqMan RNaseP Assay, ABY-QSY 20X	4485714
TaqMan RNaseP Assay, ABY-QSY PL 20X	4485715
Multiplex master mixes	
TaqMan Multiplex Master Mix, 1 mL	4461881
TaqMan Multiplex Master Mix, 5 mL	4461882
TaqMan Multiplex Master Mix, 50 mL	4486295

Other formats are available at **lifetechnologies.com/multiplexqpcr**

Calibration plates	
96-Well Calibration Plate, Mustang Purple dye	4461599
96-Well Calibration Plate, JUN dye	A24737
96-Well Calibration Plate, ABY dye	A24738

Calibration plates are also available for 96-well Fast and 384-well plate formats.
Visit **thermofisher.com/multiplexqpcr** for more information.

Find out more at **thermofisher.com/multiplexqpcr**

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TaqMan QSY probes

New quencher available for your qPCR probes

Applied Biosystems™ TaqMan™ QSY™ probes incorporate a proprietary nonfluorescent 3´ QSY quencher to provide maximal PCR performance in a multiplex format (Figure 1). Experience the sensitivity and specificity you know and expect from TaqMan™ Assays, with another great option for your real-time PCR assay designs.

Figure 1. QSY probe. The newly developed QSY quencher can be used in multiplex qPCR with FAM™, VIC™, ABY™, and JUN™ reporter dyes. The QSY quencher is nonfluorescent, leading to less background and improved quenching efficiency.

QSY probes are comparable to BHQ probes

Your current Black Hole Quencher™ (BHQ™) probe designs can easily be converted to QSY probes. Identical sequence designs can be used with similar performance using FAM dye (Figure 2) and improved performance using our ABY™ dye (Figure 3).

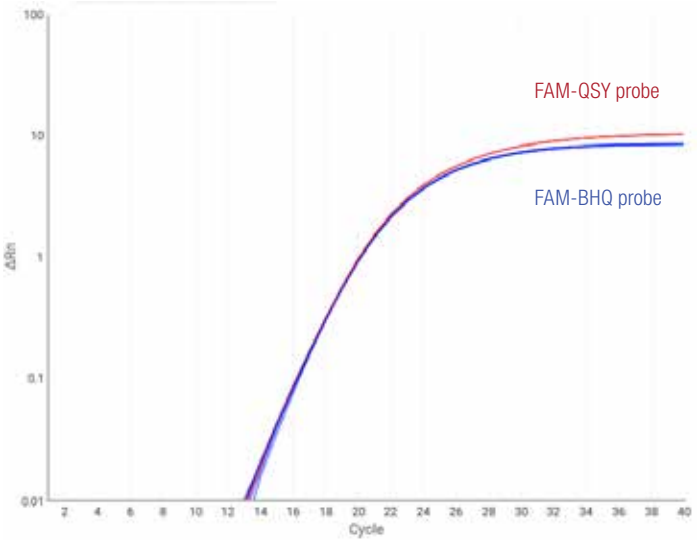

Figure 2. QSY probes have performance similar to that of BHQ probes. A FAM-QSY probe and a FAM-BHQ probe with identical oligonucleotide sequences and master mixes have similar C_t values.

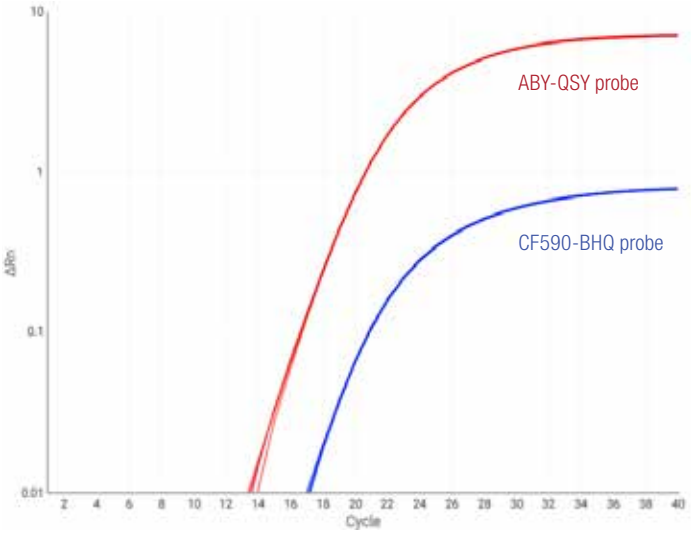

Figure 3. Improved performance in multiplex qPCR. In this multiplex experiment, the ABY-QSY probe shows a significantly lower C_t than the CF590-BHQ probe with an identical oligonucleotide sequence and master mix.

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Four dye options optimized with our instruments for better sensitivity

TaqMan QSY probes can be ordered with FAM, VIC, and our proprietary ABY and JUN dyes, allowing amplification of up to 4 targets in a single reaction. All 4 dyes are optimized for the filter sets on Applied Biosystems™ real-time PCR instruments (Figure 4) and work together with minimal spectral overlap for optimal performance.

Performance without compromise

Multiplexing with TaqMan QSY probes enables cost savings and preservation of limited samples, and also yields comparable results between reactions performed in individual tubes and in 4-plex reactions, for a gene quantification experiment (Figure 5).

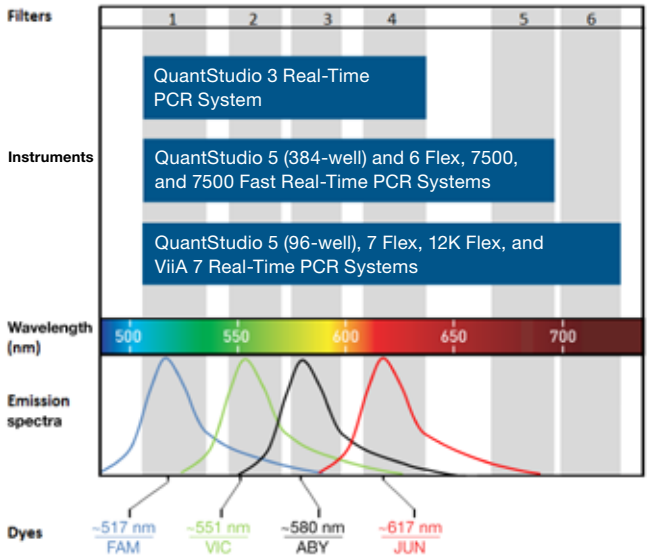

Figure 4. Fluorescence emission wavelengths used for multiplex real-time PCR. Emission spectra for FAM, VIC, ABY, and JUN dyes are shown in relation to regions of the spectrum detected by six filters available on Applied Biosystems real-time PCR instruments.

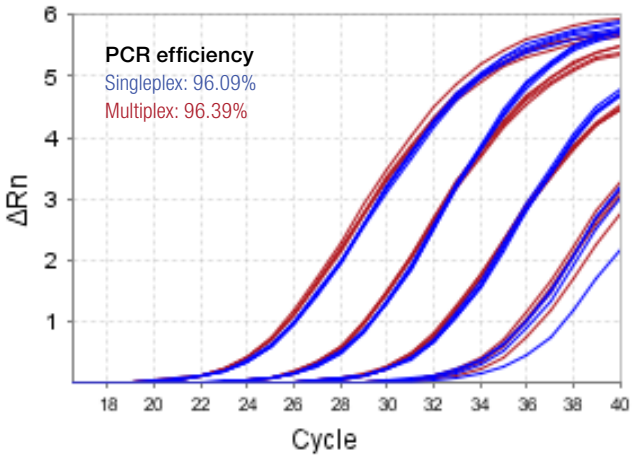

Figure 5. Comparable results for singleplex and multiplex assays. The amplification plot shows linear portions of the curves for 4 EGFR assays amplified in singleplex (blue) and 4-plex reactions (red) in a dilution series from 20,000 pg to 2 pg of reference colon cDNA per 10 µL reaction. PCR efficiencies are 96.09% for EGFR singleplex and 96.39% for EGFR 4-plex reactions.

Ordering information

Product	Quantity	Cat. No.
TaqMan QSY Probe	6,000 pmol	4482777
TaqMan QSY Probe	20,000 pmol	4482778
TaqMan QSY Probe	50,000 pmol	4482779

Product	Quantity	Cat. No.
TaqMan Multiplex Master Mix (2X)	5 mL	4461882
TaqPath 1-Step Multiplex Master Mix (4X)	5 x 1 mL	A28526
TaqPath 1-Step Multiplex Master Mix, No ROX (4X)	5 x 1 mL	A28522
Spectral Calibration Plate for Multiplex qPCR	1 plate	Various

Find out more at **thermofisher.com/multiplexqpcr**

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