ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

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Date: 2022.11.23 09:45:27 EET
Reason: MoldSign Signature
Location: Moldova

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

РАЗРЕШЕНИЕ
на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

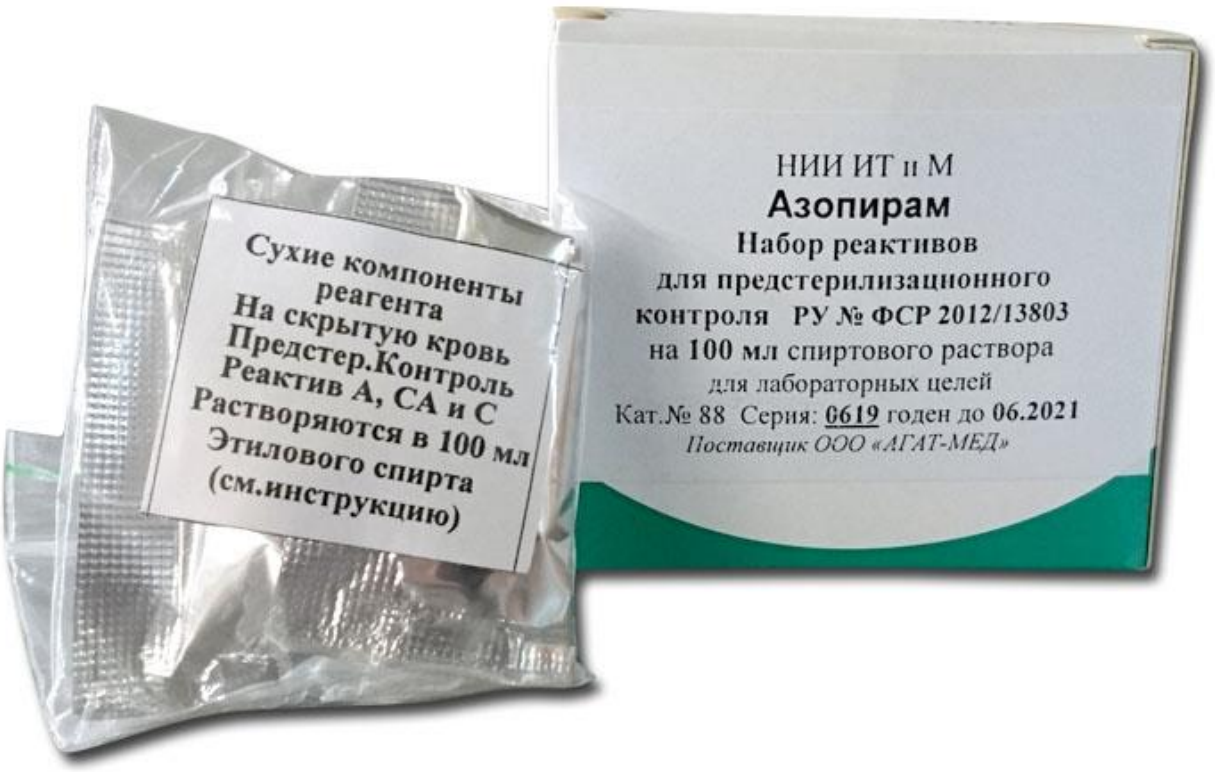
Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



Азопирам д/предстер.контроля на 100 мл, 1компл.

Реактив предназначен для контроля качества предстерилизационной очистки изделий. Применяется для выявления следов крови, которые могли остаться на подготовленных к стерилизации медицинских изделиях в результате недостаточно тщательной предстерилизационной очистки.

Хранить в сухом защищенном от света месте

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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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Organismo di Certificazione Federato CISQ
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FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
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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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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
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IAF: 12

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www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
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*
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* 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

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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

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

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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

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
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CISQ is the Italian Federation of management system Certification Bodies.

CHART PAPERS

CERACARTA

MADE IN ITALY

Widest choice of articles for a variety of sectors including:
ELECTROCARDIOGRAMS - ELECTROENCEPHALOGRAMS - FOETAL MONITORING - NEUROLOGY - GYNAECOLOGY - PNEUMOLOGY - INTENSIVE CARE UNITS - POLIGRAPHS - RESUSCITATION - ULTRASOUND SCANS - LABORATORY ANALYSIS

If requesting an offer, please state: model and instrument code, where possible the paper code and, in any case, the size. For EEG z-folds colour and line distance.

PAPERS FOR ECG

FROM THE SIMPLEST SINGLE-CHANNEL INSTRUMENTS TO THE MOST COMPLEX APPLIANCES FOR STRESS TESTS OR FOR PARTICULAR MONITORING OF CORONARY UNITS, THE BEST SOLUTION FOR ALL QUALITY AND OPERATION REQUIREMENTS CAN BE FOUND IN THE ARTICLES PRODUCED BY CERACARTA. RESEARCH AND STUDY OF THE BEST SUPPORT FOR EACH SPECIFIC APPLIANCE DERIVES FROM AN IN-DEPTH KNOWLEDGE OF THE INSTRUMENTS ON WHICH VARIOUS TYPES OF PAPER ARE USED.

Furthermore constant checks, detailed control and regular technological updating ensure continuously high efficiency in recording. For particular requirements we can supply paper which guarantees conservation of the recording trace for more than 20 years. Ceracarta always guarantees the absolute reliability of its paper with respect to all the instruments available commercially, even the less common.

PAPERS FOR CTG

THE EXTREMELY PRECISE PRINTING OF DIAGRAMS AND BASE SCALES AND THE GAUGED SENSITIVITY OF THERMAL PAPER ARE ESSENTIAL FOR THE BEST FUNCTIONING OF THE FOETAL MONITORING EQUIPMENT AND, THEREFORE, AN EXCELLENT DIAGNOSTIC READING.

Ceracarta has paid special attention to these details, manufacturing products which, also due to the perfection of the lateral holes and the numbering of each page, and owing to the accuracy of the regulating sensors, are among the best available commercially, where too often paper of insufficient efficiency is on offer. Ceracarta represents a guarantee, not found everywhere, also in the sector of foetal monitoring.

PAPERS FOR EEG

IN VIEW OF THE PARTICULAR NATURE OF EEG INSTRUMENTS AND THE DIVERSITY OF THEIR FUNCTIONS, PAPER MANUFACTURERS MUST BE EXTREMELY CAREFUL WHEN EVALUATING THE VARIOUS CHARACTERISTICS OF THE APPLIANCE AND BE VERY FLEXIBLE IN VARYING BASIC RAW MATERIALS.

A great priority must be given to the perfect running of the paper and to its excellent receptivity as for the writing pen. Through its paper Ceracarta constantly guarantees best results also in this sector, even during long recordings, thanks to its perfect adaptability, specifically and attentively researched, for all types of instruments.

PAPERS FOR ANALYSIS LABORATORY AND LABELS

THE APPARENT SIMPLICITY OF PAPERS FOR INSTRUMENTS OF ANALYSIS HAS OFTEN INDUCED CONSUMERS TO BE EASILY SATISFIED TO THE DETRIMENT OF THE QUALITY OF THE REPORT AND, ESPECIALLY OF THE CONSERVATION OVER TIME OF THE DOCUMENTATION RELATING TO THE ANALYSIS.

Also in this field, specialisation is crucial and the quality of the raw materials is of a primary importance. Ceracarta is at your disposal with rolls and packs for all types of instruments for laboratories, guaranteeing optimal functioning and a perfect result.

CERACARTA PRODUCES THERMAL PAPER LABELS, PAPERS FOR THERMAL TRANSFER PRINTERS AND POLYESTER FILMS FOR ANALYSIS LABORATORIES AND TRANSFUSION CENTRES, MANUFACTURED WITH SPECIAL MATERIALS AND ADHESIVES, FOR ALL REQUIREMENTS.

Whatever the use (labels for test tubes, medical reports, radiological envelopes or " blood bags"), an excellent outcome is ensured. Ceracarta has implemented a division for the production of labels and tickets with a microchip (RFID technology) to be applied also to the medical field.

CHART PAPERS

THE COMPANY CERACARTA

- We are leaders in Europe for the manufacturing of paper for electrical diagnostic instruments and industrial recording with over 60 years' experience in the medical sector.
- Advanced technologies, equipment and methodical quality controls for the production of specific chart and plain papers for all diagnostic equipments available on the international market.
- Superior quality materials and absolute manufacturing precision for perfect diagnosis.
- Study and research centre to meet any specific need or customisation requirement and client consulting service.
- Documents and samples sent on request.
- ISO 9001: 2015 - ISO 13485: 2016 - ISO 14001: 2015 - ISO 45001: 2018 - EC CERTIFICATION - COUNCIL DIRECTIVE 93/42/ EEC - MDR 2017/745.

THE WAREHOUSE

MACHINES AND EQUIPMENTS

WAREHOUSE

Perfect service offered to customers in terms of guaranteeing delivery times, the great care paid when choosing the most suitable form of packaging for the type of shipment, as well as the perfect correspondence between the product supplied and what is requested. • Optimal management of the stock related to production programmes: all this is guaranteed by a computerised system which now supports the traditional bar code, the revolutionary and brand-new radio frequency transponder system (TAG). • Professional skill and competence of our staff ensure an ideal service for customers.

MACHINES AND EQUIPMENTS

After the new premises were set up, the machineries have been almost completely replaced or modified in order to both improve the quality of the product and to accelerate the production process with lower costs for the customer. The whole production system has the advantage of a double check: on the one hand the specialised technical staff and the automated computer control on the other.

CE 0051
class I MD > class I MD (incl. Im)

ISO 14001 ISO 45001

CERACARTA MADE IN ITALY

Company registered with US FDA

ISO 9001:2015

EN ISO 13485:2016

Via Secondo Casadei N.14
zona industriale Villa Selva - 47122 Forlì (Italy) tel. +39.0543.780055 - fax +39.0543.781404
www.ceracarta.it - e mail: export@ceracarta.it

REV.10/2021

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.

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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 , **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

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 , **"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.

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

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