BIOSISTEM-MLD S.R.L.

IDNO: 1010600028048;
adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel. +373-22-808719, fax +373-22-808519
e-mail: biosistem.mld@gmail.com

Anexa nr. 7
la Documentația standard
conform Ordin MF Nr. 115
din 15.09.2021

CERERE DE PARTICIPARE

Către: IMSP Institutul de Cardiologie
adresa: 2025, MOLDOVA, mun.Chișinău, locality, N. Testemiteanu nr.29 bl.1

(denumirea autorităţii contractante şi adresa completă)

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene și/sau SIA RSAP MTender, nr. ocds-b3wdp1-MD-1714629083468 din 08.05.2024, privind aplicarea procedurii pentru atribuirea contractului de Set de salvare s ângelui autolog

noi, SRL Biosistem mld, am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării: 07.05.2024
Cu stimă,
Ofertant/candidat
SRL Biosistem mld _____

(semnătura autorizată)

Digitally signed by Poiata Vitalie
Date: 2024.05.07 17:07:39 EEST
Reason: MoldSign Signature
Location: Moldova

BIOSISTEM-MLD S.R.L.

IDNO: 1010600028048;
adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel. +373-22-808719, fax +373-22-808519
e-mail: biosistem.mld@gmail.com

Anexa nr. 7
la Documentația standard
conform Ordin MF Nr. 115
din 15.09.2021

DECLARAŢIE
privind valabilitatea ofertei

Către: IMSP Institutul de Cardiologie
adresa: 2025, MOLDOVA, mun.Chişinău, locality, N. Testemiteanu nr.29 bl.1
(denumirea autorităţii contractante şi adresa completă)

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea de: "Set de salvare sângelui autolog"
prin procedura de achiziție - Achiziții cu costuri mici Nr. ocds-b3wdp1-MD-1714629083468 din 08.05.2024
pentru o durată de 30 (treizeci) zile, respectiv până la data de 07.06.2024, și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 07.05.2024
Cu stimă,
Ofertant/candidat
SRL Biosistem mld _____
(semnătura autorizată)

IDNO: 1010600028048;
adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel. +373-22-808719, fax +373-22-808519
e-mail: biosistem.mld@gmail.com

BIOSISTEM-MLD S.R.L.

Anexa nr. 22
la Documentația standard
conform Ordin MF Nr. 115
din 15.09.2021

Specificaţii tehnice

Numărul procedurii de achiziție:	**ocds-b3wdp1-MD-1714629083468 din 08.05.2024**
Obiectul achiziției:	**Set de salvare sângelui autolog**

Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Modelul articolului	Țara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*
1	Set de salvare sângelui autolog	Set de salvare sângelui autolog	4256 PROCEDURE SET TX/175	Italia	Sorin,Livanova	Set de salvare sîngelui autolog compatibil cu aparatul Cell Saver SORIN GROUP Xtra ATS Auto Transfusion System	Set de salvare sîngelui autolog compatibil cu aparatul Cell Saver SORIN GROUP Xtra ATS Auto Transfusion System	ISO, CE

Semnat:_____Numele, Prenumele: Poiata Vitalie În calitate de: Administrator

Ofertantul: SRL Biosistem mld Adresa: str. Albișoara 16/1 of.7, or. Chișinău

IDNO: 1010600028048;
adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel. +373-22-808719, fax +373-22-808519
e-mail: biosistem.mld@gmail.com

BIOSISTEM-MLD S.R.L.

Anexa nr. 23
la Documentația standard
conform Ordin MF Nr. 115
din 15.09.2021

Specificații de preț

Numărul procedurii de achiziție:	**ocds-b3wdp1-MD-1714629083468 din 08.05.2024**
Obiectul achiziției:	**Set de salvare sângelui autolog**

Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Unitatea de măsură	Cantitatea	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare	Cod CPV	Clasificație bugetară (IBAN)	Discount %
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*
1	Set de salvare sângelui autolog	Set de salvare sângelui autolog	bucata	30	6 747.30	8 096.76	202 419.00	242 902.80	la solicitare, timp de 24 ore.	33100000-1	-	-
						TOTAL Oferta	**202 419.00**	**242 902.80**				

Semnat:_____Numele, Prenumele: Poiata Vitalie În calitate de: Administrator

Ofertantul: SRL Biosistem mld Adresa: str. Albișoara 16/1 of.7, or. Chișinău

BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531522** data **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**
Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociaţii:
1. POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%
Beneficiar efectiv:
1.1. POIATA VITALIE, IDNP 0983103892591,

2. NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
2.1. NASEDCHIN ALEXANDR, IDNP 2002001070747,

3. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
3.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **15.09.2023**.

Registrator în domeniul înregistrării de stat

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova

Rusu Diana

EB 0461494

Date cu caracter personal

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

Manufacturer:

Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86
41037 Mirandola MO
ITALY

Product Category(ies): **Disposable products for cardiopulmonary extracorporeal circulation (ECC), extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS); disposable products for blood processing, autotransfusion and blood monitoring systems. (as listed in the attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1292686

Valid from: 2019-06-24
Valid until: 2024-05-26

Date, 2019-06-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

Facility(ies): Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86, 41037 Mirandola MO, ITALY

Attachment:

Product Families	Classification
DIDECO KIDS ARTERIAL FILTERS: Newborn- infant Arterial filters	IIa
DIDECO MICRO: Newborn- infant, Paediatric and Adult Arterial filters / bubble traps	IIa
VENOUS / CARDIOTOMY RESERVOIRS : Venous Cardiotomy reservoirs	IIa
DIDECO CARDIOPLEGIA SETS: Cardioplegia perfusion sets including also VANGUARD, DIDECO HELIOS and CSC14 Cardioplegia heat exchangers	IIa
CARDIOACCESSORIES/DIDECO CARDIOACCESSORIES: Auxiliary devices for cardiac surgery	IIa
HEMOCONCENTRATORS: Infant, paediatric and Adult Haemoconcentrators (DHF & SH models) and sets (KH & D models)	IIa
INSPIRE: adult and small adult oxygenators	IIa
DIDECO D905 EOS Paediatric and small adult oxygenators	IIa
SYNTHESIS: adult oxygenators including also VBT 8 venous bubble trap	IIa
DIDECO KIDS: new born- infant oxygenators	IIa
DIDECO LILLI PUT 1/LILLI PUT 2: newborn infant oxygenators	IIa
REVOLUTION: centrifugal pumps for extracorporeal circulation	IIa
PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxiliary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables).	IIa
DIDECO PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxiliary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables,	IIa
DIDECO COLLECTION SYSTEMS: Autotransfusion collection systems, filters and accessories	IIa
BRAT 2: - Blood bags, collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags	IIb

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Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。
その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
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- 定期的な工場監査を実施している

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Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

- Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIa
BOWL: -Blood Bags and wash sets / autotransfusion sets including blood bags - Wash sets / autotransfusion sets without blood bags and accessories for autotransfusion	IIb IIa
ELECTA: - Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
XTRA: -Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
DIDECO DATA MASTER: Blood monitoring disposables connectors	IIa

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Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。
その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

LivaNova

Health innovation that matters

CP_MIR_TEM_000377/003

DICHIARAZIONE DI CONFORMITÀ CE

EC Declaration of Conformity

La sottoscritta

We, the undersigned

Sorin Group Italia S.r.l.
v. Statale 12 Nord, 86
41037 Mirandola (MO) - Italia

con la supervisione dell'Organismo Designato

under the supervision of the Notified Body

TÜV SÜD PRODUCT SERVICE GMBH - Identification no. 0123
Ridlerstrasse, 65
80339 München - Germany

dichiara sotto la propria responsabilità che il prodotto

herewith declare under our sole responsability that the product

XTRA

SISTEMI DI RACCOLTA / CIRCUITI MONOUSO PER AUTOTRASFUSIONE, PPP, PRP, PLT GEL, COMPRENSIVI DI SACCHE PER EMOCOMPONENTI -
SISTEMI DI RACCOLTA, CIRCUITI MONOUSO PRIVI DI SACCHE PER EMOCOMPONENTI ED ACCESSORI PER AUTOTRASFUSIONE, PPP, PRP, PLT GEL

COLLECTION SYSTEMS/ DISPOSABLE SETS FOR AUTOTRANSFUSION, PPP, PRP, PLT GEL INCLUDING BLOOD BAGS –
COLLECTION SYSTEMS/ DISPOSABLE SETS WITHOUT BLOOD BAGS AND ACCESSORIES FOR AUTOTRANSFUSION, PPP, PRP, PLT GEL.

realizzato nelle seguenti versioni

realized in the following models

CODICE	DESCRIZIONE	CLASSIFICAZIONE
04250	XTRA BOWL SET X/55	**IIb**
04250CN	XTRA BOWL SET X/55	**IIb**
04250J	XTRA BOWL SET X/55	**IIb**
04251	XTRA BOWL SET X/125	**IIb**
04251J	XTRA BOWL SET X/125	**IIb**
04251CN	XTRA BOWL SET X/125	**IIb**
04252	XTRA BOWL SET X/175	**IIb**
04252J	XTRA BOWL SET X/175	**IIb**
04252CN	XTRA BOWL SET X/175	**IIb**
04253	XTRA BOWL SET X/225	**IIb**
04253J	XTRA BOWL SET X/225	**IIb**
04253CN	XTRA BOWL SET X/225	**IIb**
04254	XTRA PROCEDURE SET TX/55	**IIb**

CODICE	DESCRIZIONE	CLASSIFICAZIONE
04254J	XTRA PROCEDURE SET TX/55	IIb
04254CN	XTRA PROCEDURE SET TX/55	IIb
04255	XTRA PROCEDURE SET TX/125	IIb
04255J	XTRA PROCEDURE SET TX/125	IIb
04255CN	XTRA PROCEDURE SET TX/125	IIb
04256	XTRA PROCEDURE SET TX/175	IIb
04256J	XTRA PROCEDURE SET TX/175	IIb
04256CN	XTRA PROCEDURE SET TX/175	IIb
04257	XTRA PROCEDURE SET TX/225	IIb
04257J	XTRA PROCEDURE SET TX/225	IIb
04257CN	XTRA PROCEDURE SET TX/225	IIb
04258	XTRA XRES T BLOOD COLLECTION RESERVOIR	IIa
04258J	XTRA XRES T BLOOD COLLECTION RESERVOIR	IIa
04258CN	XTRA XRES T BLOOD COLLECTION RESERVOIR	IIa
04259	XTRA XRES B BLOOD COLLECTION RESERV	IIa
04259CN	XTRA XRES B BLOOD COLLECTION RESERV	IIa
04274	XTRA XRES T WITH PRECONN.CARDIO KIT	IIa
04260	XTRA COLLECTION SET TX	IIa
04260CN	XTRA COLLECTION SET TX	IIa
04261	XTRA PROCEDURE SET BX/55	IIb
04261CN	XTRA PROCEDURE SET BX/55	IIb
04262	XTRA PROCEDURE SET BX/125	IIb
04262CN	XTRA PROCEDURE SET BX/125	IIb
04263	XTRA PROCEDURE SET BX/175	IIb
04263CN	XTRA PROCEDURE SET BX/175	IIb
04264	XTRA PROCEDURE SET BX/225	IIb
04264CN	XTRA PROCEDURE SET BX/225	IIb
04265	XTRA COLLECTION SET BX	IIa
04265CN	XTRA COLLECTION SET BX	IIa
04266	XTRA COLLECTION SET TX CARDIO	IIa
04266J	XTRA COLLECTION SET TX CARDIO	IIa
04267	XTRA COLLECTION SET BX CARDIO	IIa
04267J	XTRA COLLECTION SET BX CARDIO	IIa
04015	XTRA SEQUESTRATION SET X	IIb
04015J	XTRA SEQUESTRATION SET X	IIb
04268	XTRA BRB1 BLOOD REINFUSION BAG X 1L	IIb
04268J	XTRA BRB1 BLOOD REINFUSION BAG X 1L	IIb

CODICE	DESCRIZIONE	CLASSIFICAZIONE
04269	XTRA WB10 WASTE BAG X 10L	Is
04269J	XTRA WB10 WASTE BAG X 10L	Is
04275	XTRA XRES B BLOOD COLLECTION RESERVOIR - 120 µm	IIa
04276	XTRA COLLECTION SET BX - 120 µm	IIa
04277	XTRA COLLEC.SET BX CARDIO - 120 µm	IIa
04278	XTRA PROCEDURE SET BX/225 - 120 µm	IIb
04128	MULTIDIAMETER ADAPTER	IIa
04059	4 WAY ADAPTER	IIa

è in conformità con i requisiti della
is in compliance with the reference standard (s)

Direttiva 93/42/CEE del 14 giugno 1993 relativa ai dispositivi medici, Allegato II, escluso (4)
recepita con Decreto Legislativo del 24/02/1997, n. 46 e succ. modifiche

MDD 93/42/EEC dated 14th June 1993 regarding Medical Devices, as amended by Directive 2007/47/EC, Annex II, excluding (4). Transposed by LD dated 24th February 1997, n°46 and further modifications.

Il Certificato di Sistema Completo di Garanzia di Qualità n° G1 057574 0070 è stato rilasciato dall'Organismo Notificato il 24/06/2019.
Sorin Group Italia Quality System Conformity Certificate n° G1 057574 0070 has been released by Notified Body on 24th June, 2019.

Mirandola, lì 25/05/2021

Luigi Vecchi
Director, Regulatory Strategy