MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Digitally signed by Kojevnikov Dmitrii
Date: 2024.01.19 14:31:49 EET
Reason: MoldSign Signature
Location: Moldova

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice
3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri
5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate
6. Alte tipuri de comerţ cu ridicata
7. Închirierea altor maşini şi echipamente

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. 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: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	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 010244 0055 Rev. 00

Manufacturer:

Bellco S.r.l.
Via Camurana, 1
41037 Mirandola (MO)
ITALY

Facility(ies):

Bellco S.r.l.
Via Camurana, 1, 41037 Mirandola (MO), ITALY

Product Category(ies):

Haemodialysis, apheresis and blood management equipment (including accessories for monitoring of blood pressure, oxygen saturation and heart rate); haemodialysis, apheresis and blood management disposable medical devices like filters and blood lines, plasmafilters and adsorbers, cartridges for haemodialysis, powder concentrates for haemodialysis, liquid concentrates for haemodialysis

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.: ITA1315239

Valid from: 2019-07-17
Valid until: 2024-05-26

Date, 2019-07-17

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

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
- 定期的な工場監査を実施してい

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.

The right therapy way

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES
DICHIARAZIONE DI CONFORMITÀ PER DISPOSITIVI MEDICI

The Manufacturer: *Il Fabbricante:*	**Bellco S.r.l.** **Via Camurana, 1** **41037 Mirandola (MO) – Italia**
Production quality assurance system: *(Annex V of the MDD 93/42/EEC)* *Garanzia di qualità della produzione* *(Allegato V della DDM 93/42/CEE)*	**G2S 010244 0056 Rev.00**
On: *Emesso in data:*	**2019.07.18** *Valid until:* **2024.05.26** *Valido fino al:*
Certificate EN ISO 13485:2016 nr.: *Certificato EN ISO 13485:2016 no.:*	**Q5 010244 0051 Rev.01**
On: *Emesso in data:*	**2019.07.17** *Valid until:* **20241.08.31** *Valido fino al:*
Released by Notified Body: *Rilasciato dall'Organismo Notificato:*	**TÜV SÜD Product Service GmbH (id. No. 0123)** **Ridlerstraße 65 - 80339 Munich - Germany**
Herewith declares under its sole responsibility that the products:	**Accessories for haemodialysis**
Dichiara sotto la propria esclusiva responsabilità che i prodotti:	**Accessori per Emodialisi**
Description: *Descrizione:*	**See Appendix I** **Vedi Allegato I**
Classification (Annex IX of the MDD 93/42/EEC): *Classificazione (Allegato IX della DDM 93/42/CEE):*	**See Appendix I** **Vedi Allegato I**
GMDN code: *Codice GMDN*	**See Appendix I** **Vedi Allegato I**
Start of CE-Marking: *Inizio marcatura CE:*	**See Appendix I** **Vedi Allegato I**

All supporting documentation is retained at the manufacturer's premises.
The present declaration is applicable to all mentioned medical devices, manufactured by Bellco and/or anyway realized under the Manufacturer's Certified Quality System control for a period of 1 year from the approval date of the present document.

Tutta la documentazione di supporto viene mantenuta presso il produttore.
L'attuale dichiarazione è applicabile a tutti i dispositivi medici citati, prodotti da Bellco e / o comunque realizzati sotto il controllo del sistema di qualità certificato del fabbricante, per un periodo di 1 anno dalla data di approvazione del presente documento.

Mirandola, July 26th 2019

Marco Savino
Senior Quality Systems Manager

Bellco Società unipersonale a r.l.
Sede legale/fiscale, Uffici e Stabilimento:
Via Camurana, 1 - 41037 Mirandola (MO) Italy
Tel: +39 0535 29111 - Fax: +39 0535 25501
Cod. Fiscale e Partita IVA n. 06157780963
Capitale sociale € 5.000.000 i.v.
Registro Imprese di Modena n. 06157780963
Società soggetta alla direzione e al coordinamento da parte di Medtronic PLC (Irlanda)
www.bellco.net

The right therapy way

APPENDIX I TO THE DECLARATION OF CONFORMITY

This document is an integral part of the Declaration of Conformity

ALLEGATO I ALLA DICHIARAZIONE DI CONFORMITÀ

Il presente documento è parte integrante della Dichiarazione di Conformità

Last update: **July 26th 2019**
Ultimo aggiornamento:

The above-mentioned CE certificate includes the following devices:
Il Certificato CE di cui sopra include i seguenti dispositivi:

GMDN Codes/ Devices Codice GMDN/ Dispositivo	Bellco Code Codice Bellco	Models Modelli	Description Descrizione	Classification Classificazione	Classification Rule Regola di Classificazione	Start Of CE Marking Inizio Marcatura CE
32110	IB0508900	BL017	Dialysis fluid sampling accessory Accessorio prelievo liquido dialisi	Class Is Classe Is	Rule 2 Regola 2	2004
32110	IB0509200		Lympha kit accessory Accessorio per kit Lympha	Class Is Classe Is	Rule 2 Regola 2	2006
32110	IB0508600		Dialysis fluid sampling set Set prelievo bagno dialisi	Class Is Classe Is	Rule 2 Regola 2	2005
60540	IBP1397	EM702	Spike connector Raccordo perforatore	Class Is Classe Is	Rule 2 Regola 2	1998
48138	IB0560700		Priming bag connection set Set per collegamento sacche di priming	Class Is Classe Is	Rule 2 Regola 2	2000
32110	IB0561000	EM704	Autopriming adapter Adattatore per autopriming	Class Is Classe Is	Rule 2 Regola 2	2004
44942	IB0507004	BL031	2-litre drainage bag Sacca di scarico 2 lt	Class Is Classe Is	Rule 2 Regola 2	2005
44942	IB0514110		5-litre drainage bag Sacca di scarico 5 lt	Class Is Classe Is	Rule 2 Regola 2	2012
44942	IB0514111		Abylcap drainage bag Sacca di scarico Abylcap	Class Is Classe Is	Rule 2 Regola 2	2014
31667	IB0564400	BL079	Connectors closing filter Raccordi per chiusura filtro	Class Is Classe Is	Rule 2 Regola 2	1998
31667	IB0564401		Hansen connector cap Tappo chiusura Hansen	Class Is Classe Is	Rule 2 Regola 2	2012

bellco

31667	IB0564402		Hansen connector caps (coupled) Tappi chiusura Hansen (accoppiati)	Class Is Classe Is	Rule 2 Regola 2	2014
32110	IB0542601	BL194	ACIDFLEX concentrate set for Hospal – Gambro Set concentrato Acidflex per Hospal - Gambro	Class Is Classe Is	Rule 2 Regola 2	2005
32110	IB0542501		ACIDFLEX concentrate set for Fresenius Set concentrato Acidflex per Fresenius	Class Is Classe Is	Rule 2 Regola 2	2005
32110	IB0542900		Formula acid concentrate set Set per concentrato acido Formula	Class Is Classe Is	Rule 2 Regola 2	2004
36244	IB0513200	BL131	Infusion set for Amplya Linea infusione per Amplya	Class Is Classe Is	Rule 2 Regola 2	2014
36244	IB0513210		Infusion set for 5th pump Amplya Set infusione per 5a pompa Amplya	Class Is Classe Is	Rule 2 Regola 2	2014
36244	IB0513200/F		Infusion set for Amplya Linea infusione per Amplya	Class Is Classe Is	Rule 2 Regola 2	2012
36244	IB0513210/F		Infusion set for 5th pump Amplya Set infusione 5a pompa Amplyap	Class Is Classe Is	Rule 2 Regola 2	2014
36244	IB0576800		Infusion set Set per infusione	Class Is Classe Is	Rule 2 Regola 2	1998
36244	IB0576800/F		Infusion set Set per infusione	Class Is Classe Is	Rule 2 Regola 2	2010
36244	IB0595100/F	BL007	T-set for physiological saline solution with air intake Set fisiologica a T + Presa aria	Class Is Classe Is	Rule 2 Regola 2	2010
36244	IB0595800/F	BL023	Set for physiological saline solution with air Intake Set fisiologica + Presa aria	Class Is Classe Is	Rule 2 Regola 2	2010
36244	IB0595900/F		Set for physiological saline solution Set fisiologica	Class Is Classe Is	Rule 2 Regola 2	2010

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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 010244 0056 Rev. 00

Manufacturer	**Bellco S.r.l.** Via Camurana, 1 41037 Mirandola (MO) ITALY
Facility(ies):	Bellco S.r.l. Via Camurana, 1, 41037 Mirandola (MO), ITALY
Product Category(ies):	**Medical devices for extracorporeal treatments: waste bags, connectors, adaptors, infusion sets, closure caps and accessories**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:	ITA1315239
Valid from:	2019-07-18
Valid until:	2024-05-26

Date, 2019-07-18

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

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.

HAEMOPHARM BIOFLUIDS IS NOW PART OF MEDTRONIC

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES
DICHIARAZIONE DI CONFORMITA' PER DISPOSITIVI MEDICI

The Manufacturer:
Il Fabbricante:

Haemopharm Biofluids S.r.l.
Via dell'Industria, 6
23030 Tovo Di S. Agata Italy

Full Quality Assurance System Certificate nr.:
(acc. to Annex II excluding point 4) of the MDD 93/42/EEC)
Sistema completo di garanzia di qualità
(in accordo all'allegato II escluso il punto 4) della MDD 93/42/CEE)

G1 088352 0009 REV. 00

On:
Emesso in data:

16/07/2019

Valid until: **26/05/2024**
valido fino al:

Certificate ISO 13485:2016 nr.:
Certificato ISO 13485:2016 num.:

Q5 18 02 88352 007

On:
Emesso in data:

10/07/2018

Valid until: **09/07/2021**
valido fino al:

Released by Notified Body:
Rilasciato dall'Organismo Notificato:

TÜV SÜD Product Service GmbH (id. No. 0123)
Ridlerstraße 65 - 80339 Munich - Germany

Herewith declares under its sole responsibility that the products:

Dichiara sotto la propria esclusiva responsabilità che i prodotti:

Haemofiltration and dialysis solution *as per* Appendix I

Soluzioni per emofiltrazione e dialisi in Allegato I

Description:
Descrizione:

See Appendix I
vedi Allegato I

Classification (acc. to Annex IX of the MDD 93/42/EEC):
Classificazione (secondo l'allegato IX della MDD 93/42/CEE):

See Appendix I
vedi Allegato I

GMDN code:
Codice GMDN

See Appendix I
vedi Allegato I

Start of CE-Marking:
Inizio marcatura CE:

See Appendix I
vedi Allegato I

All supporting documentation is retained at the manufacturer's premises.

The products covered by the present EC Declaration bear the CE marking according to MDD 93/42/EEC (European Council Directive concerning CE marking of medical devices) and meet all the applicable provisions and the essential requirements of the Directive (transposed into the National Law D.L. n° 46 of the 24-02-1997), which allows their free distribution, sale and circulation in EEC.

The present declaration of Conformity is applicable to all mentioned medical devices, manufactured by Haemopharm Biofluids and/or anyway realized under the Manufacturer's Certified Quality System control for a period of 1 year from the approval date of the present document.

Tutta la documentazione di supporto viene mantenuta presso il produttore.

I prodotti oggetto della presente Dichiarazione CE recano la marcatura CE secondo la MDD 93/42/CEE (Direttiva del Consiglio europeo per la marcatura CE dei dispositivi medici) e rispondono a tutte le disposizioni applicabili ed ai requisiti essenziali della direttiva (recepita dal decreto legislativo DL n°46 del 24-02-1997), che consente la libera distribuzione, la vendita e la circolazione all'interno della CEE.

L'attuale dichiarazione di conformità è applicabile a tutti i dispositivi medici citati, prodotti da Haemopharm Biofluids e / o comunque realizzati sotto il controllo del sistema di qualità certificato del fabbricante, per un periodo di 1 anno dalla data di approvazione del presente documento.

Tovo di S. Agata, September 25th, 2019,

Dott.ssa Sara Bigiotti
QA

HAEMOPHARM BIOFLUIDS S.r.l. a socio unico – Cap. Soc. € 1.000.000 interamente versato
Società sottoposta ad attività di direzione e coordinamento da parte di Bellco S.r.l.
CF P.IVA reg. imp. 03222380960 R.E.A. SO-63195
Head Office and Factory: I-23030 Tovo di S.Agata (SO) - Via dell'Industria, 6 - Tel. +39 0342771015 - Fax +39 0342771500
rs.hbioamministrazione@medtronic.com hbiofluids@pec.hbiofluids.com

HAEMOPHARM BIOFLUIDS IS NOW PART OF MEDTRONIC

APPENDIX I TO THE EC DECLARATION OF CONFORMITY

This document is an integral part of the CE Declaration of Conformity

ALLEGATO I ALLA DICHIARAZIONE DI CONFORMITA' CE

Il presente documento è parte integrante della Dichiarazione di Conformità CE

Last update: **25/09/2019**
Ultimo aggiornamento:

The above-mentioned certificate includes the following devices:
Il Certificato di cui sopra include i seguenti dispositivi:

GMDN Codes *Codice GMDN*	Code *Codice*	Models *Modello*	Description *Descrizione*	Classification *Classificazione*	Classification Rule *Regola di classificazione*	Start of CE Marking *Inzio marcatura CE*
61616 - 35849	MD 021	InfoHemo D4.0	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	IB0930244	MD 022 - HMB32	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	IB0930245	MD 029- HMB34	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	IB0930246	MD 030- HMB36	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	MD 035	InfoHemo D4.0-K2,0	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e	IIb	Rule 3	2012

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Società sottoposta ad attività di direzione e coordinamento da parte di Bellco S.r.l.
CF P.IVA reg. imp. 03223880360 R.E.A. SO-63195
Head Office and Factory: I-23030 Tovo di S.Agata (SO) - Via dell'Industria, 6 - Tel. +39 0342 7710.9 - Fax +39 0342 771500
rs.hbiosamministrazione@medtronic.com biofluids@pec.hbiofluids.com

			dialisi contenuta in sacca doppia da 500+4500 ml.			
61616 - 35849	IB0930250	MD 043-HMB32	Haemofiltration and dialysis solution contained in double bag ml 500+1500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+1500 ml.	IIb	Rule 3	2012
61616 - 35849	MD 044	HMA 32	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	MD 045	HMT 32	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	MD 046	HML 45/1	Haemofiltration and dialysis solution contained in single bag ml 5000. Soluzione per emofiltrazione e dialisi contenuta in sacca singola da 5000 ml.	IIb	Rule 3	2012
61616 - 35849	MD 047	HML 45/2	Haemofiltration and dialysis solution contained in single bag ml 5000. Soluzione per emofiltrazione e dialisi contenuta in sacca singola da 5000 ml.	IIb	Rule 3	2012
61616 - 35849	MD 049	HMB 35	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	MD 053	HMB 35/1,5	Haemofiltration and dialysis solution	IIb	Rule 3	2012

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Società sottoposta ad attività di direzione e coordinamento da parte di Belico S.r.l.
CF P.IVA reg. imp. 03223380360 R.E.A. SO-63195
Head Office and factory: I-23030 Tovo di S.Agata (SO) - Via dell'Industria, 6 - Tel. +39 0342 771510 - Fax +39 0342 771500
es.hbiosamministrazione@medtronic.com hbiofluids@pec.hbiofluids.com

			contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.			
61616 - 35849	MD 065	HMT 35/2	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	MD 066	HMT 35/3	Haemofiltration and dialysis solution contained in double bag ml 500+4500. Soluzione per emofiltrazione e dialisi contenuta in sacca doppia da 500+4500 ml.	IIb	Rule 3	2012
61616 - 35849	MD 067	HML 40/1	Haemofiltration and dialysis solution contained in single bag ml 5000. Soluzione per emofiltrazione e dialisi contenuta in sacca singola da 5000 ml.	IIb	Rule 3	2012
61616 - 35849	MD 068	HML 40/1,5	Haemofiltration and dialysis solution contained in single bag ml 5000. Soluzione per emofiltrazione e dialisi contenuta in sacca singola da 5000 ml.	IIb	Rule 3	2012
61616 - 35849	MD 083	HML 40/1,5	Haemofiltration and dialysis solution contained in single bag ml 5000. Soluzione per emofiltrazione e dialisi contenuta in sacca singola da 5000 ml.	IIb	Rule 3	2019

HAEMOPHARM BIOFLUIDS S.r.l. a socio unico – Cap. Soc. € 1.000.000 interamente versato
Società sottoposta ad attività di direzione e coordinamento da parte di Bellco S.r.l.
CF P.IVA reg. imp. 03222380360 R.E.A. SO-63155
Head Office and Factory: I-23030 Tovo di S.Agata (SC) - Via dell'Industria, 6 - Tel. +39 0342710.9 - Fax +39 0342771500
rs.hbiosamministrazione@medtronic.com hbiofluids@pec.hbiofluids.com

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 088352 0009 Rev. 00

Manufacturer:
Haemopharm Biofluids S.r.l.
Via dell'Industria, 6
23030 Tovo di S. Agata (SO)
ITALY

Facility(ies):
Haemopharm Biofluids S.r.l.
Via dell'Industria, 6, 23030 Tovo di S. Agata (SO), ITALY

Product Category(ies):
Haemodialysis and Haemofiltration Solutions; Sodium Citrate Solutions; Concentrated Acid Citrated Solutions.

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.: ITA1287908

Valid from: 2019-07-16
Valid until: 2024-05-26

Date, 2019-07-16

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

The right therapy way

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES
DICHIARAZIONE DI CONFORMITÀ PER DISPOSITIVI MEDICI

The Manufacturer: *Il Fabbricante:*	**Bellco S.r.l.** **Via Camurana, 1** **41037 Mirandola (MO) – Italia**
Full Quality Assurance System Certificate nr.: *(Annex II, excluding point 4, of the MDD 93/42/EEC)* *Sistema completo di garanzia di qualità* *(Allegato II, escluso il punto 4, della DDM 93/42/CEE)*	**G1 010244 0055 Rev.00**
On: *Emesso in data:*	**2019.07.17** *Valid until:* **2024.05.26** *Valido fino al:*
Certificate EN ISO 13485:2016 nr.: *Certificato EN ISO 13485:2016 no.:*	**Q5 010244 0051 Rev.01**
On: *Emesso in data:*	**2019.07.17** *Valid until:* **2021.08.31** *Valido fino al:*
Released by Notified Body: *Rilasciato dall'Organismo Notificato:*	**TÜV SÜD Product Service GmbH (id. No. 0123)** **Ridlerstraße 65 - 80339 Munich - Germany**
Herewith declares under its sole responsibility that the mentioned products comply with the applicable requirements of MDD 93/42/EEC: *Dichiara sotto la propria esclusiva responsabilità che i prodotti citati sono conformi ai requisiti applicabili della DDM 93/42/CEE:*	**Pre-assembled devices for AMPLYA equipment** **Dispositivi pre-assemblati per apparecchiatura AMPLYA**
Description: *Descrizione:*	**See Appendix I** **Vedi Allegato I**
Classification (Annex IX of the MDD 93/42/EEC): *Classificazione (Allegato IX della DDM 93/42/CEE):*	**See Appendix I** **Vedi Allegato I**
GMDN code: *Codice GMDN*	**See Appendix I** **Vedi Allegato I**
Start of CE-Marking: *Inizio marcatura CE:*	**See Appendix I** **Vedi Allegato I**

All supporting documentation is retained at the manufacturer's premises.
The present declaration is applicable to all mentioned medical devices, manufactured by Bellco and/or anyway realized under the Manufacturer's Certified Quality System control for a period of 1 year from the approval date of the present document.

Tutta la documentazione di supporto viene mantenuta presso il produttore.
L'attuale dichiarazione è applicabile a tutti i dispositivi medici citati, prodotti da Bellco e / o comunque realizzati sotto il controllo del sistema di qualità certificato del fabbricante, per un periodo di 1 anno dalla data di approvazione del presente documento.

Mirandola, July 26th 2019

Marco Savino
Senior Quality Systems Manager

Bellco Società unipersonale a r.l.
Sede legale/fiscale, Uffici e Stabilimento:
Via Camurana, 1 - 41037 Mirandola (MO) Italy
Tel: +39 0535 29111 - Fax: +39 0535 25501
Cod. Fiscale e Partita IVA n. 06157780963
Capitale sociale € 5.000.000 i.v.
Registro Imprese di Modena n. 06157780963
Società soggetta alla direzione e al coordinamento da parte di Medtronic PLC (Irlanda)
www.bellco.net

The right therapy way

APPENDIX I TO THE DECLARATION OF CONFORMITY

This document is an integral part of the Declaration of Conformity

ALLEGATO I ALLA DICHIARAZIONE DI CONFORMITÀ

Il presente documento è parte integrante della Dichiarazione di Conformità

Last update: **July 26th 2019**
Ultimo aggiornamento:

The above-mentioned CE certificate includes the following devices:
Il Certificato CE di cui sopra include i seguenti dispositivi:

GMDN Codes/ Devices Codice GMDN/ Dispositivo	***Bellco Code Codice Bellco***	***Models Modelli***	***Description Descrizione***	***Classification Classificazione***	***Classification Rule Regola di Classificazione***	***Start Of CE Marking Inizio Marcatura CE***
Pre-assembled device for PEX treatments for AMPLYA equipment						
46998	IB0081200	ABLP05	Pre-assembled device for PEX for Amplya *Dispositivo pre-assemblato per PEX per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2014
Pre-assembled device for CPFA® treatments for AMPLYA equipment						
61674	IB0086000	ABL14P05	Pre-assembled device for CPFA for Amplya *Dispositivo pre-assemblato per CPFA per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2012
Pre-assembled device for HP treatments for AMPLYA equipment						
61674	IB0580790	ABLE	Pre-assembled device for HP for Amplya *Dispositivo pre-assemblato per HP per Amplya*	Class IIa *Classe IIa*	Rule 3 *Regola 3*	2015
Pre-assembled devices for RRT treatments for AMPLYA equipment						
61674	IB0087030	ABL03	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2014
61674	IB0087050	ABL05	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2014
61674	IB0087080	ABL08	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2014
61674	IB0087140	ABL14	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2012

61674	IB0087170	ABL17	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2014
61674	IB0087220	ABL22	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2014
61674	IB0580903	ABLD03	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2016
61674	IB0580905	ABLD05	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2016
61674	IB0580908	ABLD08	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2016
61674	IB0580914	ABLD14	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2016
61674	IB0580917	ABLD17	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2016
61674	IB0580922	ABLD22	Pre-assembled device for RRT for Amplya *Dispositivo pre-assemblato per RRT per Amplya*	Class IIb *Classe IIb*	Rule 3 *Regola 3*	2016