Digitally signed by Kojevnikov Dmitrii
Date: 2019.02.13 17:42:54 EET
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII **Nr.** 044647

Denumirea autorității de licențiere	**Camera de Licențiere**
Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență	**Societatea Comercială „OXIVIT-MED" S.R.L.** mun.Chișinău, bd. Decebal, 82, ap. 90
Data și numărul certificatului de înregistrare de stat a titularului de licență	30.07.2007 MD 0067985
Numărul de înregistrare a întreprinderii sau IDNO	1007600044280
Codul fiscal	
Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența	*** Importul și comercializarea dispozitivelor medicale ***
Data eliberării licenței	15 octombrie 2012
Valabilă pînă la Prelungită pînă la: 15.10.2022	15 octombrie 2017

Semnătura conducătorului autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

MOBIAS BANCA

Nr. 12101-504

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.Ş.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

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

Funcţia, numele, prenumele persoanei care a eliberat certificatul

semnătura

MD 0067985

L.Ş.

„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **71** din **05.01.2016**

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 și codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;
2 Comerțul cu ridicata al parfumurilor și produselor cosmetice;
3 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerț cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerț cu ridicata;
7 Închirierea altor mașini și echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociați:
1. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 5400.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 05.01.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA * CAMERA ÎNREGISTRĂRII DE STAT Î.S. * 1004600077171 * 101 *

AA6 * EA * 0346843EA

c/f: 10037600044280; adresa: str. Independenței 28-34, 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	09723015012362

ORDIN DE PLATA nr. 10 | DATA EMITERII 12 02 2019 | TIP.DOC. 1

PLATITI 16000.00 LEI Sasesprezece Mii lei 00 bani

PLATITOR (R) S.C. "OXIVIT-MED" S.R.L.
Cod IBAN MD44ML0000000022517295O3
CODUL FISCAL 1007600044280

PRESTATORUL PLATITOR suc. "Invest"
CODUL BANCII MOLDMD2X329

BENEFICIAR (R) IMSP SPITALUL CLINIC MUNICIPAL "SFANTA TREIME"
Cod IBAN MD22ML0000000022516661 4
CODUL FISCAL 1003600152592

PRESTATORUL BENEFICIAR suc. "Alecu Russo"
CODUL BANCII MOLDMD2X366

DESTINATIA PLATII
Pentru garantia pentru oferta la licitatia publica nr. ocds-b3wdp1-MD-1548335546618 din 14.02.2019

TIPUL TRANSFERULUI NORMAL/URGENT
N

L.S.

CODUL TRANZACTIEI 001
DATA PRIMIRII 12 02 2019
DATA EXECUTARII 12 02 2019 17:44:00

SEMNATURILE EMITENTULUI

SEMNATURA PRESTATORU

B.C. «MOLDINDCONBANK» S.A.
mun. Chişinău
EX 12 februarie 2019
MD-2012, Republica Moldova,
mun. Chişinău, str. Armenească, 38.

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016
ISO 9001:2015

Scope:
Sales, order management, warehousing and distribution of medical devices.
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021
Certificate effective date: 1 July 2018
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

MGMT. SYS.
RvA C 589

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:	Different scope
Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices including technical service and customer education. Warehousing and distribution of medical devices, including spine loaner operations
Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy	Sales, order management and distribution of medical devices. Including technical service and customer education. Promotion, invoice and order management of medicinal products.
Medtronic Danmark A/S. Arne Jacobsens Allé 17 2300 Kopenhagen Denmark	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic Medikal Teknoloji Ticaret Ltd Sti Saray Mah. Esnaf Sk. Akkom Ofis Park Laodik Plaza Sitesi B Blok Apt: 2/8 00000 Umraniye - Istanbul Turkey	Sales, order management and distribution of medical devices. Including technical service and customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd. Waterfall Distribution Campus CNR K101 and Bridal Veil Road Waterfall Midrand 1685 Gauteng South Africa	Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.
Medtronic Ibérica S.A. Calle de María de Portugal, 11 28050 Madrid Spain	Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.
Medtronic Romania SRL Ploiesti 42-44, Building B, B2 Wing, 2nd floor, district 1 Baneasa Business & Technology Park 013696 Bucharest Romania	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic Norge AS Martin Linges vei 25 1364 Fornebu Norway	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic Portugal, LDA- Avenida Gomes Pereira 61B Benfica 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices Including technical service and customer education. Warehousing and distribution of medical devices, including spine loaner operations.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Service & Repair CoE C-Mill gebouw K Jan Campertstraat 21-A 6416 SG Heerlen	Service and repair of medical devices (excluding Imaging and Navigation products).
Medtronic Ibérica S.A. Polígono Industrial La Garena Calle Francisco Rabal 7 28806 Alcalá De Heneras, Madrid Spain	Spine loaner operations.
Medtronic Ibérica S.A. WTC Almeda Park Placa de la Pau, s/n. Edificio 7, 3 piso 08940 Cornellà de Llobregat, Barcelona Spain	Warehousing and distribution of medical devices, including spine loaner operations
Medtronic France SAS 27/33 Quai Alphonse Le Gallo 92513 Boulogne-Billancourt France	Sales, order management and distribution of medical devices. Including technical Service and customer education
Medtronic Trading NL B.V. Larixplein 4 5616 VB Eindhoven	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic GmbH Earl-Bakken-Platz 1 40670 Meerbusch Germany	Distribution of medical Devices, medical equipment and related services.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Osterreich GmbH Milennium Tower, 20th floor Handelskai 94-96 1200 Wien Austria	Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education
Medtronic (Schweiz) AG Talstrasse 9 3053 Munchenbuchsee Switzerland	Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education
Medtronic Hellas S.A. Avenue Kifisias 24 Building B 151 25 Marousi Pref. Attica Greece	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic Serbia Ltd. Bulevar Zorana Djindjica, 64a 11070 Belgrade Serbia	Sales, order management and distribution of medical devices.
Medtronic Hungária Kft. Bocskai út 134-146 Cépület 3. emelet 1113 Budapest Hungary	Sales, order management and distribution of medical devices. Including customer education.
Medtronic CCO SSC Warsaw Polna 11 00-633 Warszawa Poland	Order management of medical devices.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Finland Oy Lentäjäntie 3 01530 Vantaa Finland	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic AB P.O. Box 1034 164 21 Kista Sweden	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic Trading Ltd. 10 Hamada Street 4673344 Herzlya Israel	Import, sales, order management and distribution of medical devices. Including technical service and customer education

Addendum expiry date: 1 July 2021
Addendum effective date: 1 July 2018

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 84868**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

In respect of:

The design, development and manufacture of Endoluminal Stent Grafts and Delivery Systems for Endovascular Indications, Stent Graft Balloon Catheters, Renal Stents and Delivery Systems, Iliac Stents and Delivery Systems, Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems, Coronary Stents and Delivery Systems, Intravascular Catheters and Guidewires for diagnostic or interventional procedures and Catheter Systems for Renal Denervation and Vascular Introducer Sheaths.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **24 August 2004** Date: **01 July 2016** Expiry Date: **23 August 2019**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**01 July 2016**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
ADMEDES Schuessler GmbH Rastatter Strasse 15 75179 Pforzheim Germany	**Manufacture**
Flextronics International GmbH Niederlassung Althofen Friesacher Strasse 3 9330 Althofen Austria	**Manufacture**
INVATEC S.p.A Via Martiri della Libertà 7 Roncadelle (BS) 25030 Italy	**Manufacture**
Medistri SA Rte de l'Industrie 96 Case Postale 115 1564 Domdidier Switzerland	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**01 July 2016**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen Netherlands	**EU Representative**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**Design** **EU Representative** **Manufacture**
Medtronic Mexico EG Carret. Int. Km. 1969 Guad.-Nogales Km.2 Empalme, Sonora 85340 Mexico	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**01 July 2016**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Vascular 3576 Unocal Place Santa Rosa CA 95403 USA	**Design**
Plexus Corp. Pinnacle Hill Kelso TD5 8XX United Kingdom	**Manufacture**
Plexus Manufacturing SDN BHD Bayan Lepas Free Industrial Zone Phase II, 11900 Bayan Lepas Penang Malaysia	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**01 July 2016**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
SSP-SiMatrix, Inc 1131 North US Highway 93, Victor, Montana 59875 USA	**Manufacture**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Synergy Health Ireland Limited IDA Business & Technology Park Tullamore Offaly Ireland	**E beam Sterilization** **ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 84868**
Date:	**01 July 2016**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health Sterilization UK Limited Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**E beam Sterilization**
Synergy Health Westport Limited Lodge Road Westport County Mayo Ireland	**Gamma Sterilization**
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **01 July 2016**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
24 August 2004		First Issued
15 November 2014		Transfer of the following certificates from NSAI:- Q252.322, Q252.407, Q252.426, Q252.427, Q252.428, Q252.467, Q252.480, Q252.587, and Q252.611 D252.587 and D252.407, plus incorporation of Medtronic Vascular Ireland as a subcontract manufacturer
02 December 2004		Carotid and Coronary Stents and Delivery Systems added to the scope (transfer) Medtronic Mexico (manufacture), and Titan Scan Systems, Nutec Corporation, Sterigenics (Queensbury), Steris Corporation-Isomedix Services (Sandy), Rocialle in Health (Mid Glamorgan UK), and EBIS Iotron added as sub-contract sterilizers
21 December 2004		PCTA Balloon Dilatation Catheters added to the range of products manufactured (transferred from another Notified Body) and Isotron Ireland Ltd added as sub-contract sterilization site
19 August 2005		Sterilization sub-contractor name change from Titan Scan Systems to Beam One
03 April 2006		Addition of Sterigenics UK Ltd, as sterilization sub-contractor
07 August 2006		Addition of AD)MEDES Schuessler GmbH as a sub-contractor for manufacture

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **01 July 2016**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
11 January 2008	7149866	Subcontractor name change from EBIS Isotron, Harwell to Isotron Harwell. Addition of Isotron plc, Daventry as a subcontractor for E beam sterilization.
03 October 2008	7279045	Addition of Medtronic Mexico EG, Empalme as a subcontractor for manufacture.
14 April 2009	7341499	Correction of the legal name of the Medtronic Mexico facility and postcode for the Isotron PLC, Daventry facility. Addition of the activity of EU Representative for Medtronic Ireland.
13 August 2009	7432878	Certificate renewal. Addition of Accellant Inc as a manufacturing subcontractor, amendment to company name for Isotron PLC, Daventry, and Steris Corporation, Sandy, Utah. Change to address for the subcontractor, Nutek Corporation. Addition of E Beam Sterilization for Isotron Ireland. Rewording of scope for clarification purposes only.
29 July 2010	7546410	Added C.R. Bard, Inc. to the list of significant subcontractors for manufacturing. Extended the scope to include guidewires.
12 October 2011	7730209	Extension to scope to include Catheter Systems for Renal Denervation. Removal of Carotid Stents and Delivery Systems from the scope. Minor amendments to Isotron Daventry and Isotron Tullamore's addresses.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **01 July 2016**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
26 January 2012	7792125	Amendment to significant subcontractors to reflect Isotron's name change to Synergy Health and removal of Isotron Harwell.
25 May 2012	7842435	Amendment to the address format and zip code for the significant subcontractor Medtronic Mexico (Tijuana).
19 December 2012	7915649	Addition of Medtronic B.V. The Netherlands for EU Representative Activities.
22 January 2013	7945194	Extension to scope to include Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems.
28 February 2013	7960715	Addition of Invatec Technology Center GmbH to the list of significant subcontractors for manufacturing activities.
28 March 2013	7943883	Extension to Scope to include Vascular Introducer Sheaths and the addition of Teleflex Medical for manufacturing activities.
16 December 2013	8082854	Addition of Plexus Manufacturing Sdn Bhd, Malaysia and Plexus Corp, UK to the list of significant subcontractors for manufacturing activities.
13 July 2014	8154862	Certificate Renewal. Various updates and changes to the list of significant subcontractors. Correction of the reference number for the reissue dated 19th December 2012 on the certificate history page

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **01 July 2016**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
31 July 2015	8350802	Addition of SSP SiMATrix Inc. as balloon supplier for the Attain Clarity
01 July 2016	8545838	C. R. Bard, Inc., Medtronic Ardian LLC, Nutek Corporation, Sterigenics NY and Apical Instruments Inc. were removed from the list of significant subcontractors.

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60124973 0001

Report No.: 16801466 007

Manufacturer:
MEDPLUS INC.
4th Floor, Building C-4,
Gaosha Industrial Zone
ZhongCun, Panyu District
Guangzhou
Guangdong Province 511495*
China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: DD 60080068 0001

Expiry Date: 2022-12-23

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-12-24

Date: 2017-12-19

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60124973 0001
Report No.: 16801466 007

Manufacturer:
MEDPLUS INC.
4th Floor, Building C-4
Gaosha Industrial Zone
ZhongCun, Panyu District
Guangzhou
Guangdong Province 511495
China

Products:
- Breathing Circuits
- Biopsy Needles
- Anesthesia Masks
- Breathing Bags

Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Tourniquets
- Skin Markers
- Sterile Needle Magnetizers
- Sterile Caps
- Loss of Resistance Syringes for Single Use

Sites included:

No.126, Guangshao Road, Aotou Town, Conghua District, Guangzhou, 510945 Guangdong Province, China

5th Floor, Building C-4, Gaosha Industrial Zone, ZhongCun, Panyu District, Guangzhou, 511495 Guangdong Province, China

Notified Body

Date: 2017-12-19

X. Ren

TÜV Rheinland LGA Products GmbH Certifizierungsstelle

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

MEDPLUS INC.
4th Floor, Building C-4,
Gaosha Industrial Zone
ZhongCun, Panyu District
Guangzhou
Guangdong Province 511495
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-12-24
Certificate Registration No.:	SX 60124977 0001
An audit was performed. Report No.:	16801466 007
This Certificate is valid until:	2020-12-23

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2017-12-19

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax. +49 221 806-3935 e-mail.cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60124977 0001
Report No.: 16801466 007

Organization:
MEDPLUS INC.
4th Floor, Building C-4,
Gaosha Industrial Zone
ZhongCun, Panyu District
Guangzhou
Guangdong Province 511495
China

Medplus Inc

Scope:

Products:

- Breathing Circuits
- Biopsy Needles
- Loss of Resistance Syringes for Single Use
- Anesthesia Masks
- Breathing Bags
- Tourniquets
- Skin Markers
- Suction Liners
- Needle Magnetizers
- Sterile Caps

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

Date: 2017-12-19

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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4th Floor, Building C-4,
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ZhongCun, Panyu District
Guangzhou
Guangdong Province 511495
China

广州麦普医疗器械制造有限公司 Medplus Inc

Scope:

Sites included:

No.126, Guangshao Road, Aotou Town, Conghua District, Guangzhou, 510945 Guangdong Province, China

Manufacture of Anesthesia Masks

5th Floor, Building C-4, Gaosha Industrial Zone, ZhongCun, Panyu District, Guangzhou, 511495 Guangdong Province, China

Warehouse

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

X. Ren

Date: 2017-12-19