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ORDIN DE PLATA NR.: 11                                TIP.DOC. 1 :
                                DATA EMITERII:17 ianuarie 2020 :
=====:
PLATITI: 9200-00                                LEI: Noua Mii Doua Sute lei 00 bani :
:
:
=====:
PLATITOR: (R) S.C. "OXIVI          CONTUL DE PLATI/CODUL IBAN :
T-MED" S.R.L.                      MD44ML000000002251729503 :
                                CODUL FISCAL :1007600044280 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau          :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP Institu          CONTUL DE PLATI/CODUL IBAN :
tul de medicina urgenta              MD55VI022510300000002MDL :
                                CODUL FISCAL :1003600152606 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
B.C."VICTORIABANK"S.A.                  :VICBMD2X :
=====:
DESTINATIA PLATII:Pentru garantia pentru:      TIPUL TRANSFERULUI :
oferta la procedura de achizitie public:        NORMAL/URGENT :N:
a nr.ocds-b3wdpl-MD-1575902612455 din 20:      :
.01.2020                                         :
:                                               :
:                                               :
:                                               L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
                                DATA PRIMIRII:17/01/2020 : SEMNATURILE :
                                DATA EXECUTARII:          : EMITENTULUI :
                                :-----:
CONducator:Web Kojevnikov Dmitrii :
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:
(semnatura electronica) :
CONTABIL-SEF:Web Kojevnikov Dmitrii :
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:
:
L.S. (semnatura electronica) :
CONducator: (semnatura manuala) :
CONTABIL-SEF: (semnatura manuala) :
SEMnatura PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
-----:

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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

MD 0067985





„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 vânzarea 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
tel. 022-266-252



Lazari Aliona



Gessate, 7 February 2012

CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC
as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

- A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).
- B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

GIMA S.p.A.
Q.A. Department
Nicola Manzoni





Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

Quality Management System Certificate ISO 9001:2015

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid until	2021-10-14		

Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C

DECLARATION OF CONFORMITY

Manufacturer

Grena Limited
1000 Great West Road
Brentford, Middlesex, TW8 9HH
United Kingdom

Product(s)

Disposable circular staplers with related surgical instruments (class IIb, rule 8)
Disposable linear staplers and cartridges for linear staplers (class IIb, rule 8)
Disposable bone marrow aspiration needles (class IIa, rule 6)
Disposable bone marrow biopsy needles (class IIa, rule 6)
Disposable staples cartridges for reusable linear staplers (class IIb, rule 8)
Disposable staples cartridges for reusable circular staplers (class IIb, rule 8)
Disposable endoscopic linear cutting staplers (class IIa, rule 6)
Cartridges for disposable endoscopic linear cutting staplers (class IIb, rule 8)
Surgical meshes (class IIb, rule 8)
Disposable automatic clip appliers with clips (class IIb, rule 8)
LigaV® – Titanium ligating clips (class IIb, rule 8)
VClip® – Titanium ligating clips (class IIb, rule 8)
Click'a-V® – Polymer ligating clips (class IIb, rule 8)

Disposable endoscopic instruments:

Disposable grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
Disposable grasper with ratchet-Allis (class IIb, rule 9)
Disposable grasper with ratchet-Maxi Grip (class IIb, rule 9)
Disposable toothed grasper with ratchet (class IIb, rule 9)
Disposable grasper with ratchet –Babcock (class IIb, rule 9)
Disposable Metzenbaum scissors-curved (class IIb, rule 9)
Disposable scissors-straight (class IIb, rule 9)
Disposable scissors-hook (class IIb, rule 9)
Disposable dissector-Maryland (class IIb, rule 9)
Disposable dissector with ratchet- Maryland (class IIb, rule 9)
Disposable endoscopic dissector 3mm – Maryland, non-ratcheted
Disposable endoscopic dissector 3mm – Maryland, ratcheted
Disposable endoscopic grasper 3mm – atraumatic fenestrated
Disposable endoscopic scissors 3mm – curved

Limited use endoscopic instruments:

Limited use dissector- Maryland (class IIb, rule 9)
Limited use dissector with ratchet- Maryland (class IIb, rule 9)
Limited use Metzenbaum scissors- curved (class IIb, rule 9)
Limited use scissors-straight (class IIb, rule 9)
Limited use scissors-hook (class IIb, rule 9)
Limited use grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
Limited use disposable grasper with ratchet-Allis (class IIb, rule 9)
Limited use grasper with ratchet-Maxi Grip (class IIb, rule 9)
Limited use toothed grasper with ratchet (class IIb, rule 9)
Limited use grasper with ratchet –Babcock (class IIb, rule 9)

Reusable endoscopic surgical instruments (class IIb, rule 9)
Disposable linear cutting staplers and cartridges for cutting staplers (class IIb, rule 8)
Disposable trocars with accessories (class IIa, rule 7)
Sterile disposable skin staplers (class IIa, rule 7)
Thoracentesis/paracentesis sets (class IIa, rule 6)
Suction cannulas and suction sets (class IIa, rule 7)
Suction-irrigation sets (class IIa, rule 6)
Disposable skin staples removers (class I sterile, rule 1)
Chest drainage systems (class I sterile, rule 1)
Connecting tubes (class I sterile, rule 1)
Retrieval bags (class IIa, rule 6)
Veress needles (class IIa, rule 6)
Silicone slings (class IIa, rule 6)
Arida® absorbing pads (class I, rule 1)
Arida® absorbing pads – sterile (class I sterile, rule 1)
Solidifying agent (class I, rule 1)
Open surgery and endoscopic clip appliers (class I, rule 6)
Vomit bags (class I, rule 1)



VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH, UK

Phone +44 131 208 207 6 Fax +44 131 777 80 77

Classification

According to Annex IX of Directive 93/42/EEC

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the directive 93/42/EEC concerning medical devices which apply to them. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

Notified Body

C E 0197

TÜV Rheinland LGA Products GmbH
Lillystrasse 2
90431 Nürnberg
Germany

EC Certificate(s)

HD 60040590 0001
DD 60040589 0001

Brentford, 09.05.2014

Wiesław Brodaczewski
Director

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom**

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

**Design and development, production and distribution
of disposable and reusable medical devices for surgical and
patient care procedures. Servicing of suction devices.
(see attachment for site 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: 2018-06-29
Certificate Registration No.: SX 60130220 0001
An audit was performed. Report No.: 26300270 007
This Certificate is valid until: 2021-04-13

Certification Body



Date 2018-06-29

Maciej Sciera
Maciej Sciera



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>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60130220 0001
Report No.: 26300270 007

Organization: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Scope:

Site included:

Grena Ltd.
Chelsea House
Chelsea Street
Nottingham NG7 7HP
United Kingdom

Activity: Design and development, production
and distribution of disposable and reusable
medical devices for surgical and patient care
procedures. Especially: production, purchasing,
logistics and distribution of disposable
and reusable medical devices.

Certification Body



Date: 2018-06-29

Maciej Sciera

Maciej Sciera



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

Registration No.: DD 60100980 0001

Report No.: 26300270 002

Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

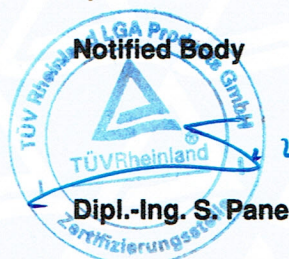
Products: (see attachments for products and site included)
Replaces approval, registration no.: DD 60040589 0001

Expiry Date: 2020-04-13

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: 2015-04-30

Date: 2015-04-30



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60100980 0001
Report No.: 26300270 002

Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Products included:

- Disposable trocars
- Infusion sets
- Retrieval bags
- Disposable skin staplers
- Suction cannulas and suction sets
- Thoracentesis/Paracentesis sets
- Transfusion sets
- Veress needles
- Thoracic catheters
- Suction-irrigation sets
- Silicone slings

For the following medical devices the scope covers
only the aspects of manufacture concerned with securing
and maintaining sterile conditions:

- Disposable skin staples removers
- Chest drainage systems
- Connecting tubes
- Absorbing pads

Date: 2015-04-30



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

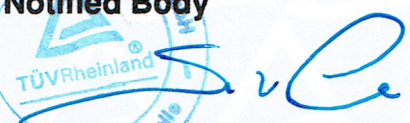
Registration No.: DD 60100980 0001
Report No.: 26300270 002

Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Date: 2015-04-30


Notified Body

Dipl.-Ing. S. Pane

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60100981 0001

Report No.: 26300270 002

Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

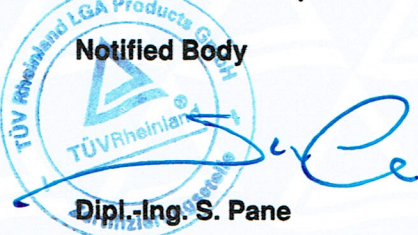
Products: (see attachments for products and site included)
Replaces approval, registration no.: HD 60040590 0001

Expiry Date: 2020-04-13

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2015-04-30

Date: 2015-04-30

Notified Body

Dipl.-Ing. S. Pane

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.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60100981 0001
Report No.: 26300270 002

Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Products included:

- Reusable endoscopic surgical instruments
- Disposable endoscopic surgical instruments
- Disposable linear cutting staplers with cartridges
- Disposable linear staplers with cartridges
- Disposable circular staplers with related surgical instruments
- Staples cartridges for reusable circular staplers
- Staples cartridges for reusable linear staplers
- Ligating clips
- Surgical meshes
- Cartridges for disposable endoscopic linear cutting staplers
- Disposable endoscopic linear cutting staplers

Date: 2015-04-30



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

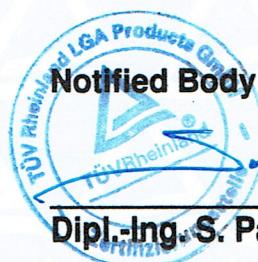
Registration No.: HD 60100981 0001
Report No.: 26300270 002

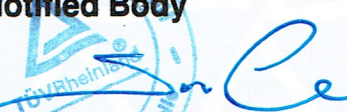
Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Date: 2015-04-30




Dipl.-Ing. S. Pane

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

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

**Design and development, production and distribution
of disposable and reusable medical devices for surgical and
patient care procedures
(See attachment for site included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2015-04-30
Certificate Registration No.: SX 60100982 0001
An audit was performed. Report No.: 26300270 002
This Certificate is valid until: 2018-04-13

Certification Body



Date 2015-04-30



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>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to
Registration No.: SX 60100982 0001
Report No.: 26300270 002

Organization: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Scope: Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Distribution

Certification Body



Date: 2015-04-30



Dipl.-Ing. S. Pane

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

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

**Design and development, production and distribution
of disposable and reusable medical devices for surgical and
patient care procedures
(see attachment for site included)**

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

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

Effective Date: 2015-04-30
Certificate Registration No.: SY 60100983 0001
An audit was performed. Report No.: 26300270 002
This Certificate is valid until: 2018-04-13

Certification Body

Date 2015-04-30



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>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SY 60100983 0001
Report No.: 26300270 002

Organization: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Scope: Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Distribution

Date: 2015-04-30

**Certification Body**

Dipl.-Ing. S. Pane

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

Registration No.: OD 69250737 0001

Report No.: 28228813 001

Manufacturer: R VENT MEDIKAL URETIM A.S.
29 Ekim Mah. Balkan Cad. No:33, Yazibasi beldesi,
Torballi, Izmir 35860
TURKEY

Products: See attachment for complete product list

The Notified Body audited the quality system, and certifies 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, Article 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.

Issue Date: 2015-10-01

Notified Body

Effective Date: 2015-10-01

Expiry Date: 2020-09-30



Ambrus Zoltán
Ambrus Zoltán MD

Page: 1 / 2

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, <http://www.tuv.com/hun/>

TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.

ATTACHMENT

Registration No.: OD 69250737 001

Report No.: 28228813 001

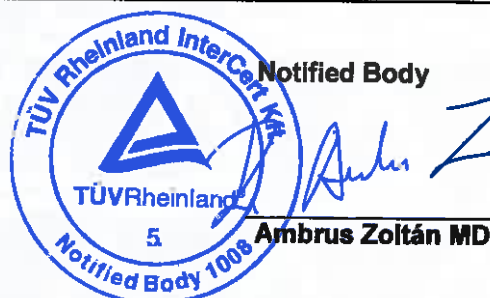
Manufacturer: R VENT MEDIKAL URETIM A.S.
29 Ekim Mah. Balkan Cad. No:33, Yazibasi beldesi, Torbali, Izmir
35860

Products:

GMDN code	REF (if different from Name). Name
37704	ANAESTHESIA CIRCUIT
37706	BREATHING CIRCUIT
36990	BIPAP CIRCUITS
36700	CPAP CIRCUITS
37706	IPPB CIRCUITS
37706	HEATED WIRE CIRCUITS
37706	COAXIAL CIRCUITS
35890	GAS SAMPLING LINES
34838	CATHETER MOUNTS
10123	CONNECTORS
35113	HUMIDIFIER CHAMBER
37597	HME FILTER
31311	BACTERIAL-VIRAL FILTER
37597	TRACHEOSTOMY FILTERS
34923	CLOSED SUCTION SYSTEMS
12449	AEROSOL MASK
12450	OXYGEN MASKS
35176	ANAESTHESIA MASKS
31254	MASKS STRAP
35203	OXYGEN THERAPY SETS
35202	AEROSOL THERAPY SETS
36086	DISPOSABLE BVM RESUSCITATOR
41863	ANAESTHESIA BAG

Budapest, 2015-10-01

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TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, <http://www.tuv.com/hun/>

TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.

Certificate

The Certification Body of
TÜV Rheinland InterCert Kft.

hereby certifies that the company

R VENT MEDIKAL URETIM A.S.

**29 Ekim Mah. Balkan Cad.
No:33, Yazibasi beldesi, Torbali, Izmir 35860
TURKEY**

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

**Manufacturing and Distribution of sterile and non-sterile
disposable medical devices used in anesthesia and
intensive care.**

Proof has been furnished that the requirements of

EN ISO 13485:2012+AC:2012

are fulfilled. The certification is subject to periodic surveillance.

Certificate Registration No.: **OY 69250740 001**

Audit report No.: **28228813 001**

This certificate is valid: **from 2015-10-01 to 2018-09-30**

2015-10-01
Date of issue



Ambrus Zoltán MD
Certifier

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, <http://www.tuv.com/hun/>

Certificate

The Certification Body of
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**29 Ekim Mah. Balkan Cad.
No:33, Yazibasi beldesi, Torbali, Izmir 35860
TURKEY**

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

**Manufacturing and Distribution of sterile and non-sterile
disposable medical devices used in anesthesia and
intensive care.**

Proof has been furnished that the requirements of

MSZ EN ISO 13485:2012

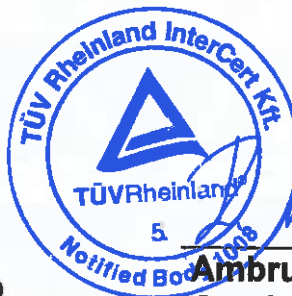
are fulfilled. The certification is subject to periodic surveillance.

Certificate Registration No.: **OX 69250739 001**

Audit report No.: **28228813 001**

This certificate is valid: **from 2015-10-01 to 2018-09-30**

2015-10-01
Date of issue




Ambrus Zoltán MD
Certifier

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, <http://www.tuv.com/hun/>

Certificate

The Certification Body of
TÜV Rheinland InterCert Kft.

hereby certifies that the company

R VENT MEDIKAL URETIM A.S.

**29 Ekim Mah. Balkan Cad.
No:33, Yazibasi beldesi, Torbali, Izmir 35860
TURKEY**

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

**Manufacturing and Distribution of sterile and non-sterile
disposable medical devices used in anesthesia and
intensive care.**

Proof has been furnished that the requirements of

ISO 9001:2008

are fulfilled. The certification is subject to periodic surveillance.

Certificate Registration No.: **MQ 69250751 001**

Audit report No.: **28228813 001**

This certificate is valid: **from 2015-10-01 to 2018-09-30**

2015-10-01
Date of issue




Ambrus Zoltán MD
Certifier

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, <http://www.tuv.com/hun/>

TT 01-T32



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 16 02 77608 012

Manufacturer:**Covidien Inc**

15 Hampshire Street
Mansfield, MA 02048
USA

EC-Representative:**Covidien Ireland Limited**

IDA Business and Technology Park
Tullamore
IRELAND

**Product
Category(ies):**

Medical Instruments, Surgical Products
and Hemostatic Materials:

- Surgical Suture Products, Pledgets and Retention Tapes
- Endoscopy Instruments and Accessories
including Lubricant
- Surgical Staple, Clip Products and Accessories
- Manual Surgical Instruments
- Implantable Wound Dressing Materials
- Ultrasonic Surgical Devices and Accessories
- Suction / Irrigation Devices and Accessories
- Arthroscopy Implants, Instruments and Accessories
- Bone Wax
- Temporary Cardiac Pacing Lead

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.:

713078138

Valid from:

2016-04-17

Valid until:

2021-04-16

Date, 2016-04-05

Stefan Preiß



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

Page 1 of 2



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 16 02 77608 012**Facility(ies):**

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731,
USA

Covidien (Davis & Geck Caribe, Ltd.)
Zona Franca de San Isidro, Carretera San Isidro Km 17, Santo
Domingo, DOMINICAN REPUBLIC

Covidien
Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C.,
MEXICO

Covidien Deutschland Manufacturing GmbH
Gewerbepark 1, 93333 Neustadt/ Donau, GERMANY

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

Covidien Medical Products (Shanghai) Manufacturing L.L.C.
Building#10,789 Puxing Road, 201114 Shanghai, PEOPLE'S
REPUBLIC OF CHINA

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

© Integral publication of this certificate and adjoining reports is allowed



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 Copenhagen
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 Österreich GmbH
Millennium 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
Céptület 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
Lentäjätie 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