Digitally signed by Palii Nina
Date: 2020.04.29 17:22:25 EEST
Reason: MoldSign Signature
Location: Moldova

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 01233**

Issued To:

Carestream Health, Inc.
150 Verona Street
Rochester
New York
14608
USA

In respect of:

The design, development and manufacture of diagnostic image recording devices including storage phosphor screens and reader systems, medical x-ray films, direct digital radiography systems, dental x-ray systems including film, dental and medical imaging equipment, and medical imaging and PACS Software. Those aspects of metrology related to the design and manufacture of dimensional measuring PACS software.

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 2797):

Albert Roossien, Regulatory Lead

First Issued: **1996-03-06** Date: **2019-02-27** Expiry Date: **2021-03-05**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as detailed above and the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party unless your company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: +31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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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 01233**

Date: **2019-02-27**

Issued To: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Agfa-Gevaert HealthCare GmbH Bürgermeister-Götz-Str. 10 Schrobenhausen 86529 Germany	**Manufacture**
Algotec Systems Ltd 2 Hapnina Street PO BOX 46 43107 Ra'anana Israel	**Design** **Development** **Software**
Analogic Corporation 8 Centennial Drive Peabody Massachusetts 01960 USA	**Design** **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 01233**
Date:	**2019-02-27**
Issued To:	**Carestream Health, Inc.** **150 Verona Street** **Rochester** **New York** **14608** **USA**

Subcontractor:	**Service(s) supplied**
Carestream Health France 1, rue Galilée 93192 NOISY-LE-GRAND CEDEX France	**EU Representative**
Carestream Health, Inc 5450 Campus Drive Canandaigua New York 14424 USA	**Manufacture**
Carestream Health, Inc. 1049 West Ridge Road Rochester New York 14615 USA	**Design** **Development** **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 01233**
Date:	**2019-02-27**
Issued To:	**Carestream Health, Inc.** **150 Verona Street** **Rochester** **New York** **14608** **USA**

Subcontractor:	**Service(s) supplied**
Carestream Health, Inc. 1669 Lake Avenue Rochester New York 14652 USA	**Design** **Development** **Manufacture**
Carestream Health, Inc. 1964 Lake Ave Rochester New York 14615 USA	**Design**
Carestream Health, Inc. 2000 Howard Smith Avenue West Windsor Colorado 80550 USA	**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 01233**

Date: **2019-02-27**

Issued To: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Carestream Health, Inc. 8124 Pacific Avenue White City Oregon 97503 USA	**Manufacture**
Carestream Health, Inc. Global R & D Center (Shanghai) No. 27 Xinjinqiao Road Shanghai 201206 China	**Design Development**
Communication & Power Industries Canada Inc. 45 River Drive Georgetown Ontario L7G 2J4 Canada	**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 01233**

Date: **2019-02-27**

Issued To: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Micro-X Ltd 1284 South Road Clovelly Park South Australia 5042 Australia	**Design** **Manufacture**
Rayco (Shanghai) Medical Products Company Limited Building 7, No. 1510 Chuanqiao Road China (Shanghai) Pilot Free Trade Z Shanghai 201206 China	**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 01233**
Date:	**2019-02-27**
Issued To:	**Carestream Health, Inc.** **150 Verona Street** **Rochester** **New York** **14608** **USA**

Subcontractor:	**Service(s) supplied**
Rayco (Xiamen) Medical Products Company Limited 308 Wengjiao Road Haicang District Xiamen Fujian 361022 China	**Manufacture**
ScImage, Inc. 4916 El Camino Real, Suite 200 Los Altos California 94022 USA	**Design** **Development** **Software**

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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 01233**

Date: **2019-02-27**

Issued To: **Carestream Health, Inc.**
150 Verona Street
Rochester
New York
14608
USA

Subcontractor:	Service(s) supplied
Soluciones Médicas Exportación S de RL de CV Calle Anillo Periferico Poniente No. 3100 Colonia Paraísos Del Colli Zapopan Jalisco 45069 Mexico	Manufacture
Varian Medical Systems, Inc. X-Ray Products 1678 South Pioneer Road Salt Lake City Utah 84104 USA	Manufacture

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Carestream Health, Inc
150 Verona Street
Rochester
New York
14608
USA

Holds Certificate No: **FM 701584**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, distribution, (integration, installation and servicing excluding film products) of diagnostic image recording devices, photo chemicals, medical and dental imaging systems, cone beam computed tomography, information technology software for healthcare information systems and medical imaging and detection. Manufacture, service, installation and distribution of Dry View Printers. Storage, Handling, Packaging and Distribution of Pharmaceutical Products.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-12-20
Latest Revision Date: 2019-09-24

Effective Date: 2019-10-03
Expiry Date: 2022-10-02

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Certificate No: **FM 701584**

Location	Registered Activities
Carestream Health, Inc 150 Verona Street Rochester New York 14608 USA	The design, manufacture, distribution, (integration, installation and servicing excluding film products) of diagnostic image recording devices, photo chemicals, medical dental imaging systems, cone beam computed tomography, information technology software for healthcare information systems and medical imaging and detection. Manufacture, service, installation and distribution of Dry View Printers. Storage, Handling, Packaging and Distribution of Pharmaceutical Products.
Carestream Health Inc. 1600 Lexington Ave. Suite #356 Rochester New York 14606 USA	Storage, Handling, Packaging and Distribution of Finished Devices, and Replacement Parts, the Storage, Handling, Packaging and Distribution of Pharmaceutical Products.
Carestream Health, Inc. Smart System Technology and Commercialization Center (STC) 5450 Campus Drive Canandaigua New York 14424 USA	The manufacture of X-ray detectors.
Carestream Health, Inc 1049 West Ridge Road Rochester New York 14615 USA	The assembly, integration and distribution of image management systems. The design and manufacture of cassettes, and intensifying and storage phosphor screens. The design, manufacture, service, and installation of medical x-ray equipment systems, cone beam computed tomography, medical imaging systems including software and accessories.
Carestream Health, Inc 1669 Lake Avenue Rochester New York 14652 USA	The manufacture of dental and medical x-ray films, intensifying and Storage phosphor screen chemicals. The design and development of dental x-ray film systems and media used in medical imaging.
Carestream Health, Inc 1964 Lake Avenue Rochester New York 14652 USA	The design and development of dental x-ray film systems and media used in medical imaging.

Original Registration Date: 2008-12-20

Latest Revision Date: 2019-09-24

Effective Date: 2019-10-03

Expiry Date: 2022-10-02

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Carestream Health, Inc
150 Verona Street
Rochester
New York
14608
USA

Holds Certificate No: **FM 537916**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design, development, manufacture, and service of digital radiography imaging systems (such as INDUSTREX digital systems) and accessories for the non-destructive testing industry.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2008-07-17
Latest Revision Date: 2019-09-24

Effective Date: 2019-10-21
Expiry Date: 2022-10-20

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Certificate No: **FM 537916**

Location	Registered Activities
Carestream Health, Inc 150 Verona Street Rochester New York 14608 USA	The design, development, manufacture, and service of digital radiography imaging systems (such as INDUSTREX digital systems) and accessories for the non-destructive testing industry.
Carestream Health, Inc 1049 West Ridge Road Rochester New York 14615 USA	The design and manufacture of digital radiography imaging systems (such as INDUSTREX digital systems) and accessories for the non-destructive testing industry.

Original Registration Date: 2008-07-17
Latest Revision Date: 2019-09-24

Effective Date: 2019-10-21
Expiry Date: 2022-10-20

Consumabile pentru servicul rad | 89.32.230.138:8081

Не защищено | 89.32.230.138:8081

Приложения | Mail.Ru | Google | Поиск в Интернете | Google | Объекты в продаже | Загрузки | Friv | Redirecting | chemical-products-... | Search Results | Autentificare | Другие закладки

AGENTIA MEDICAMENTULUI SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
1.3. Certificatul CE	Certificat CE
1.2. Declaratia de conformitate CE	Declaratia de conformitate CE
1.2. Declaratia de conformitate CE	Declaratia de conformitate CE_2

Введите текст для поиска...

Nr	Denumire	Denumire...	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vi
		CARESTREAM				carest				
DM000003671	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 20 X 40 CM, N 100	525 3422	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003666	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 13 X 18 CM, N 100	525 3349	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003670	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 18 X 43 CM, N 100	146 3116	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003668	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 15 X 40 CM, N 100	526 8370	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003673	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 35 X 35 CM, N 100	164 0820	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003667	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 18 X 24 CM, N 100	811 6428	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003672	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 30 X 40 CM, N 100	129 0527	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003669	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 24 X 30 CM, N 100	166 6007	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003674	FILM RADIOGRAFIC PENTRU UZ GENERAL	CARESTREAM MXG	GREEN, 35 X 43 CM, N 100	190 1909	SUA	CARESTREAM HEALTH, INC	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	

Contains([Producatorul], 'carest') in Contains([NameMake], 'CARESTREAM MXG')

15:56
25.11.2019

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
	rege					cares	m-inter		
DM000003488	DEVELOPATOR ŞI REGENERATOR PENTRU FILME CU RAZE X	CARESTREAM X-OMAT EX II	LICHID, 2 PCS. X 20 L	527 4394	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019
DM000003469	FIXATIV ŞI REGENERATOR PENTRU FILME CU RAZE X	RETINA XCF	LICHID, 2 PCS. X 20 L	523 6138	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019
DM000003482	DEVELOPATOR ŞI REGENERATOR PENTRU FILME CU RAZE X	CARESTREAM GBX	LICHID, 2 PCS. X 25 L	515 8621	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019
DM000003485	DEVELOPATOR ŞI REGENERATOR PENTRU FILME CU RAZE X	RETINA XCE	LICHID, 2 PCS. X 20 L	523 9130	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019
DM000003490	FIXATIV ŞI REGENERATOR PENTRU FILME CU RAZE X	CARESTREAM RP X-OMAT LO	LICHID, 2 PCS. X 20 L	522 4381	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019

✓ Содержит [Representant] 'm-inter' И Содержит [Producatorul] 'cares' И Содержит [Denumire]...

REPUBLICA MOLDOVA, CHIȘINĂU, SOCIETATEA INTER-FARM

AGENTIA MEDICAMENTULUI SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

	Denumire
sclaratia de conformitate CE	Declaratia de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
	dezv					carest	m-inter			
DM000003486	DEVELOPATOR SI REGENERATOR PENTRU FILME CU RAZE X	CARESTREAM X-OMAT EX II	LICHID, 2 PCS. X 20 L	527 4594	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003481	DEVELOPATOR PENTRU FILME CU RAZE X	RETINA XPE	PRAF, 7 PCS. X 15 L	270 2867	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003482	DEVELOPATOR SI REGENERATOR PENTRU FILME CU RAZE X	CARESTREAM GBX	LICHID, 2 PCS. X 25 L	515 8621	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	
DM000003485	DEVELOPATOR SI REGENERATOR PENTRU FILME CU RAZE X	RETINA XCE	LICHID, 2 PCS. X 20 L	523 9330	SUA	CARESTREAM HEALTH, INC.	M-INTER-FARMA S.A.	Rg04-000272	05-11-2019	

Compare([Reprezentant], 'm-inter') И Compare([Producatorul], 'carest') И Compare([Denumire],... Очистить

Carestream

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares that the product(s) listed are made in conformity with:
Medical Device Directive [Directive 93/42/EEC], ANNEX II Conformity Assessment Procedure and the Australian Therapeutic Goods (Medical Devices) Regulations 2002, Clause 1.8 of Schedule 3.

Manufacturer's Name and Address:	Carestream Health, Inc. 150 Verona Street Rochester, New York, USA 14608
Medical Device:	X-ray Film, Sheet
Product List:	X-OMAT BT Film Medical X-ray Blue / MXB Film Medical X-ray Blue / MXBE Film Medical X-ray Green / MXG Film T-MAT G/RA Film T-MAT L/RA Film INSIGHT Pediatric Film INSIGHT Thoracic Film X-SIGHT G/RA Film MIN-R EV Film MIN-R S Film MIN-R 2000 Plus Film L Green X-ray Film WB HG Green X-ray Film WB Green X-ray Film WB Full Blue X-ray Film WB Mammo Film WB —End of List—
Device Classification:	Europe - Class IIa, ANNEX IX , Rule 16 Australia - Class IIa, Schedule 2, Part 5, Rule 5.4
GMDN Code and Term:	40979. Medical x-ray film, screen
Scope of Application	All declared products

Each kind of medical device to which the quality-management system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full-quality-assurance procedures at each stage, from the design of the device until its final inspection before being supplied.

Quality-Management-System	Certified to EN ISO 13485 by BSI No. FM 701584 BSI No. FM 507315 DNV No. 245266-2017-AQ-USA-NA-PS Rev. I BSI No. FM 46141 TUV No. Q2N 17 11 61500 005
European Notified Body:	British Standards Institute, BSI (2797)
Full-Quality-Assurance-System Certificate (CE):	BSI Certificate Number CE 01233
European Authorized Representative:	Carestream Health France 1, rue Galilée 93192 NOISY-LE-GRAND CEDEX FRANCE

The relevant sections of the following European Union Harmonized standards apply to the listed product(s):

EN ISO 14971
EN 1041
EN ISO 15223-1
EN 62366

Treya D. R. Collins
Director, Global Quality Systems
Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608, USA
Telephone: +1-970-304-4654

Carestream

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares that the product(s) listed are made in conformity with:

Medical Device Directive [Directive 93/42/EEC], ANNEX VII Conformity Assessment Procedure and the Australian Therapeutic Goods (Medical Devices) Regulations 2002, Clause 6.6 of Schedule 3.

Manufacturer's Name and Address:

Carestream Health, Inc.
150 Verona Street
Rochester, New York, USA 14608

Medical Device:

Medical Imaging Photoprocessing Devices - Photochemicals

Product List:

Chemistry used to develop or fix the image on medical and dental X-ray films:
GBX Developer and Replenisher
GBX Fixer and Replenisher
GBX Twin Pack
X-OMAT MX Fixer and Replenisher
X-OMAT MX Developer and Replenisher
READYMATIC Developer and Replenisher
READYMATIC Fixer and Replenisher
READYMATIC Chem Pack
RP X-OMAT Developer and Replenisher
RP X-OMAT LO Fixer and Replenisher
X-OMAT EX II Developer and Replenisher
X-OMAT Developer Starter
X-OMAT LE+ Developer and Replenisher
X-OMAT LE+ Fixer and Replenisher
CARESTREAM DENTAL X-ray Monobath
CARESTREAM DENTAL X-ray Developer
CARESTREAM DENTAL X-ray Fixer
Rapid Access Twin Pack
Rapid Access Developer
Rapid Access Fixer
XCE Developer and Replenisher
XCF Fixer and Replenisher
XPE Developer
XPF Fixer
—End of List—

Device Classification:

Europe - Class I, ANNEX IX, Rule 1
Australia - Class I, Schedule 2, Part 2, Rule 2.1

GMDN Code and Term:

41009 Radiographic film processing chemical, automated
41008 Radiographic film processing chemical, manual

Scope of Application All declared products

Each kind of medical device to which the Declaration of Conformity (not requiring assessment by the Secretary) procedures have been applied complies with the applicable provisions of the essential principles and the classification rules before being supplied

European Authorized Representative: Carestream Health France
1, rue Galilée
93192 NOISY-LE-GRAND CEDEX
FRANCE

The relevant sections of the following European Union Harmonized standards apply to the listed product(s):

EN 1041
EN ISO 15223-1
EN ISO 14971
EN 62366

Kevin C. Wright
Senior Director, Worldwide Regulatory Affairs
Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608, USA
Telephone: +1-585-627-6878

ybm BELGELENDİRME

SERTİFİKA
CERTIFICATE

BEREN MEDİKAL PAZARLAMA SAN. TİC. LTD. ŞTİ.

İOSB FATİH SAN SİT 3B BLOK NO:3-4 BAŞAKŞEHİR / İSTANBUL

MEDİKAL KAYIT KAĞITLARI VE ULTRASON PRİNTER KAĞITLARI TASARIMI VE ÜRETİMİ, YOĞUN BAKIM CİHAZLARI KURULUM, MONTAJ VE TEKNİK SERVİSİ

PRODUCTION AND SALES OF MEDICAL RECORD&CHART PAPERS. ULTRASOUND IMAGING PAPERS, INSTALLATION AND AFTERSALES TECHNICAL SERVICES OF INTENSIVE CARE DEVICES

kapsamında
with a scope of

ISO 13485:2016

Tıbbi Cihazlar Kalite Yönetim Sistemine uygun bir sistem kurmuştur.
has established that is in compliance with the Medical Devices Quality Management System Standard.

Sertifika No : *MDD1024*
Certificate No.

İlk Yayın Tarihi : *19.07.2019*
Initial Date

Sertifika Yayın Tarihi / Rev No : *19.07.2019/00*
Date of This Certificate / Rev.No.

Sertifika Geçerlilik Tarihi : *18.07.2020*
Certificate Expiry Date

Yeniden Belgelendirme Tarihi : *18.07.2022*
Date of Re-Certification

UNITED ACCREDITATION FOUNDATION UAF

Zühtü Özdemir
GENEL MÜDÜR
General Manager

Bu belge YBM'nin belgelendirme kurallarına uyulması ve periyodik ara denetimlerin başarıyla tamamlanması kaydıyla geçerlidir. Daha fazla bilgi için lütfen bizi arayınız.
This certificate is effective if it is complied with the certification rules of YBM and periodic surveillance audits are completed successfully. Please call us for more information.

Yönetim Belgelendirme Merkezi Test ve Gözetim Hizmetleri Ltd. Şti.
Teşvikiye Mah. Dilli Sok. No:1-3 Kat: 1 D.4 Zeytinburnu / İstanbul Tel: 0212 547 31 00
info@ybm.com.tr www.ybm.com.tr

EC Declaration of Conformity

EC Declaration of Conformity Class I devices to Medical Devices Directive 93/42/EEC

Manufacturer: Ultragel Hungary 2000 Ltd.
Manufacturer's Address: HU 1023 Budapest, Bécsi út 4.
Device/s: **Ultrasound gels,**
Aquaultra Basic
Aqusultra Clear
Aquaultra Aloe
HYPERSCAN100
Aqua-VET
Aqua-LUB
Aqua-LUB20
Aqua-LUB5

EC Product Class: Class I in accordance with Annex IX, Rule 1.

Declaration of Conformity

Ultragel Hungary 2000 Ltd. declares that Ultrasound gels listed above conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and EC Council Directive 2007/47/EC dated 5 September 2007 and it is in accordance with EN ISO 9001:2008, as implemented by the European Union's Medical Devices Regulations.

Ultragel Hungary 2000 Ltd. agrees to develop, implement and maintain a formally-recognised EN ISO 9001:2008 Quality Management System to ensure continued adequacy and efficacy.

Ultragel Hungary 2000 Ltd. confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Ultragel Hungary 2000 Ltd. agrees In EC Council Directive 93/42/EEC dated 14 June 1993 appendix meets the essential requirements and provides capabilities intended by the manufacturer. Under normal conditions will not endanger the patient, the operator or other person in the health and safety.

Ultragel Hungary 2000 Ltd. agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Signed by the Ultragel Hungary 2000 Ltd. designated representative:

Name: __Komáromy Balázs_____ Title: Managing director

Date: 04.05.2017.

Ultragel Hungary 2000 Kft.
Sz.h.: 1023 Budapest, Bécsi út 4.
Adószám: 13870975-2-41
Banksz.: 10300002-10314636-49020021
5

Ultragel Hungary 2000 Kft.
1023 Budapest Bécsi út 4.
info@ultragel.hu
+36 1 278 3050
www.ultragel.hu