

Anexa 1. Unitate ecografica

Specificarea tehnică deplină solicitată	Specificatia tehnica ofertata Versana Premier (GE Healthcare)
Ecograf multidisciplinar, staționar conceput pentru examinări abdominale, obstetrice și ginecologice, părți moi, musculoscheletale, vasculare/sistem vascular periferic, urologice, pediatrie, transcraniale, cardiace, veterinare.	Ecograf multidisciplinar, staționar conceput pentru examinări abdominale, obstetrice și ginecologice, părți moi, musculoscheletale, vasculare/sistem vascular periferic, urologice, pediatrie, transcraniale, cardiace, veterinare.
CARACTERISTICI CONSTRUCTIVE, STRUCTURALE ȘI DIMENSIONALE	CARACTERISTICI CONSTRUCTIVE, STRUCTURALE ȘI DIMENSIONALE
Sistem staționar cu următoarele caracteristici:	Sistem staționar cu următoarele caracteristici:
- patru roți pentru stabilitatea în deplasarea și poziționarea cu posibilitate de blocare a cel puțin 2 roți	- patru roți pentru stabilitatea în deplasarea și poziționarea cu posibilitate de blocare a cel puțin 2 roți
- roțile să poată fi blocate pentru deplasarea în linie dreaptă	- roțile să poată fi blocate pentru deplasarea în linie dreaptă
Tehnologie modernă la gabarit redus:	Tehnologie modernă la gabarit redus:
Dimensiunea ecografului: 1475 x 525 x 740 mm	Dimensiunea ecografului: 1475 x 525 x 740 mm
Echipamentul nu cântărește mai mult de 60 kg	Echipamentul nu cântărește mai mult de 60 kg
Consum maxim: 240 VA + inclusiv cu periferice	Consum maxim: 240 VA - inclusiv cu periferice
Echipament prevăzut cu 3 porturi active pentru traductori de tip imagine	Echipament prevăzut cu 4 porturi active pentru traductori de tip imagine
Posibilitatea instalării celui de-al 4-lea port	Posibilitatea instalării celui de-al 4-lea port
Consolă cu filtre de particule. Acestea pot fi accesate și curățate ușor, fără a fi nevoie de instrumente suplimentare sau de demontare.	Consolă cu filtre de particule. Acestea pot fi accesate și curățate ușor, fără a fi nevoie de instrumente suplimentare sau de demontare.
Sistem cu difuzoare integrate pentru frecvențe joase ce asigură o acustică fidelă	Sistem cu difuzoare integrate pentru frecvențe joase ce asigură o acustică fidelă
Consolă prevăzută cu un sistem de asigurare al cablurilor	Consolă prevăzută cu un sistem de asigurare al cablurilor
Suport integrat pentru tubul de gel	Suport integrat pentru tubul de gel
DESCRIEREA CONSOLEI	DESCRIEREA CONSOLEI
Monitor de tip LED de înaltă rezoluție	Monitor de tip LED de înaltă rezoluție
Diagonala monitorului: 21,5"	Diagonala monitorului: 21,5"
Posibilitate de ajustare a luminozității și contrastului monitorului	Posibilitate de ajustare a luminozității și contrastului monitorului
INTERFAȚA CU UTILIZATORUL	INTERFAȚA CU UTILIZATORUL
Ecran de comandă tactil de tip LED	Ecran de comandă tactil de tip LED
Diagonala ecranului de comandă tactil: 10.4"	Diagonala ecranului de comandă tactil: 10.4"
Tastatură alfanumerică ergonomică pentru introducerea pacienților	Tastatură alfanumerică ergonomică pentru introducerea pacienților
Interfața software oferă posibilitatea de a fi editată pentru crearea unor profiluri individuale de utilizator	Interfața software oferă posibilitatea de a fi editată pentru crearea unor profiluri individuale de utilizator
Echipamentul dispune de platforma ce oferă utilizatorului suport tehnic la distanță atât în domeniul de aplicații cât și pentru cel service prin accesare rapidă	Echipamentul dispune de platforma ce oferă utilizatorului suport tehnic la distanță atât în domeniul de aplicații cât și pentru cel service prin accesare rapidă
Această platformă permite monitorizarea de la distanță, suport în timp real pentru aplicații și probleme de diagnoză	Această platformă permite monitorizarea de la distanță, suport în timp real pentru aplicații și probleme de diagnoză
MODURI DE OPERARE	MODURI DE OPERARE
Moduri de funcționare fundamentale:	Moduri de funcționare fundamentale:
- mod de tip M	- mod de tip M
- mod de tip 2D	- mod de tip 2D
- mod Doppler (Color, Power, Spectral)	- mod Doppler (Color, Power, Spectral)
Moduri de funcționare derivate și/sau combinate din cele fundamentale:	Moduri de funcționare derivate și/sau combinate din cele fundamentale:
- M Color	- M Color
- Doppler Spectral Pulsat	- Doppler Spectral Pulsat
- HPRF	- HPRF
Capacitate de a funcționa cu 3 moduri de lucru active în același timp (triplex)	Capacitate de a funcționa cu 3 moduri de lucru active în același timp (triplex)
TIPURI DE TRADUCTORI COMPATIBILI CU ECOGRAFUL	TIPURI DE TRADUCTORI COMPATIBILI CU ECOGRAFUL
Adâncimea minimă de scanare: < 0.5 cm	Adâncimea minimă de scanare: < 0.5 cm
Adâncimea maximă de scanare: > 32.5 cm	Adâncimea maximă de scanare: > 33 cm
Traductori de tip:	Traductori de tip:
- convex (convex, micro-convex endocavitar 2D, convex volumetric) acoperă în întregime domeniul 2-10 MHz	- convex (convex, micro-convex endocavitar 2D, convex volumetric) acoperă în întregime domeniul 2-10 MHz
- micro-convex pediatric ce prezintă câmpul de vizualizare de 128°	- micro-convex pediatric ce prezintă câmpul de vizualizare de 128°
- micro-convex 2D ce prezintă câmpul de vizualizare de 132° folosită în pediatrie	- micro-convex 2D ce prezintă câmpul de vizualizare de 132° folosită în pediatrie
- micro-convex biplan ce acoperă în întregime domeniul 3 - 11 MHz	- micro-convex biplan ce acoperă în întregime domeniul 3 - 11 MHz

- liniar ce acoperă în întregime domeniul 4-13 MHz	- liniar ce acoperă în întregime domeniul 4-13 MHz
- sectorial arie fazată acoperă în întregime domeniul 1 - 5 MHz	- sectorial arie fazată acoperă în întregime domeniul 1 - 5 MHz
- permite lucru cu sonda convexa 3D planar	- permite lucru cu sonda convexa 3D planar
- permite lucru cu sonda convexa 3D integral	- permite lucru cu sonda convexa 3D integral
OBTINEREA ȘI AFIȘAREA IMAGINII	OBTINEREA ȘI AFIȘAREA IMAGINII
Formator de unde digital	Formator de unde digital
Peste 220.000 de canale efective digitale de procesare	Peste 225.792 de canale efective digitale de procesare
Rata de reîmprospătare a imaginii: aproximativ 1.400 cadre/secundă (dependent de traductor și aplicație)	Rata de reîmprospătare a imaginii: 1.447 cadre/secundă (dependent de traductor și aplicație)
Gama dinamică: aproximativ 260 dB	Gama dinamică: 260 dB
Optimizare automată a imaginii la nivel de pixel, pentru reducerea interacțiunii operatorului cu echipamentul	Optimizare automată a imaginii la nivel de pixel, pentru reducerea interacțiunii operatorului cu echipamentul
În vederea îmbunătățirii calității imaginii, echipamentul încorporează o tehnică de procesare adaptivă a imaginii prin analiza comparativă a tuturor pixelilor ce formează imaginile, în relație cu pixelii din imediata vecinătate	În vederea îmbunătățirii calității imaginii, echipamentul încorporează o tehnică de procesare adaptivă a imaginii prin analiza comparativă a tuturor pixelilor ce formează imaginile, în relație cu pixelii din imediata vecinătate
Tehnologie de compunere spațială a mai multor cadre obținute prin interogarea din mai multe unghiuri ale aceleiași zone de interes, având ca scop întărirea conturilor structurilor vizualizate, reducerea diverselor artefacte și îmbunătățirea rezoluției de contrast	Tehnologie de compunere spațială a mai multor cadre obținute prin interogarea din mai multe unghiuri ale aceleiași zone de interes, având ca scop întărirea conturilor structurilor vizualizate, reducerea diverselor artefacte și îmbunătățirea rezoluției de contrast
Compunerea spațială a mai multor imagini ale aceleiași zone scanate într-una singură este posibilă pentru reducerea zgomotului de fond și este compatibilă cu următoarele moduri de lucru/tehnici:	Compunerea spațială a mai multor imagini ale aceleiași zone scanate într-una singură este posibilă pentru reducerea zgomotului de fond și este compatibilă cu următoarele moduri de lucru/tehnici:
Echipamentul prezintă posibilitatea lărgirii câmpului vizual la funcționarea cu traductori liniari în scopul afișării pe ecran a unor zone suplimentare de țesut – imagine trapezoidală	Echipamentul prezintă posibilitatea lărgirii câmpului vizual la funcționarea cu traductori liniari în scopul afișării pe ecran a unor zone suplimentare de țesut – imagine trapezoidală
MODURI DE AFIȘARE A IMAGINILOR	MODURI DE AFIȘARE A IMAGINILOR
Posibilitate de afișare a imaginilor ecografice în modul 2D astfel:	Posibilitate de afișare a imaginilor ecografice în modul 2D astfel:
- Stânga/Dreapta (atât în modul live cât și în post-procesare)	- Stânga/Dreapta (atât în modul live cât și în post-procesare)
- Imagine 2D Color	- Imagine 2D Color
Afișare simultană a imaginii 2D în scală de gri și a imaginii 2D color posibilă în modul Doppler Color	Afișare simultană a imaginii 2D în scală de gri și a imaginii 2D color posibilă în modul Doppler Color
Posibilitate de afișare multi-imagine (imagine live și imagine înghețată)	Posibilitate de afișare multi-imagine (imagine live și imagine înghețată)
BAZĂ DE DATE PACIENȚI	BAZĂ DE DATE PACIENȚI
Echipamentul înglobează o bază de date pacienți capabilă să stocheze date demografice ale acestora, imagini statice și în mișcare, rapoarte	Echipamentul înglobează o bază de date pacienți capabilă să stocheze date demografice ale acestora, imagini statice și în mișcare, rapoarte
Formatul de stocare a imaginilor asociate pacienților este unul brut și permite la accesarea ulterioară a pacienților modificarea:	Formatul de stocare a imaginilor asociate pacienților este unul brut și permite la accesarea ulterioară a pacienților modificarea:
- Amplificării (la toate modurile de lucru - M, 2D, Doppler Color, Power, spectral)	- Amplificării (la toate modurile de lucru - M, 2D, Doppler Color, Power, spectral)
- Baseline și unghi de corecție la modul de lucru Doppler spectral	- Baseline și unghi de corecție la modul de lucru Doppler spectral
Informațiile stocate în baza de date au posibilitatea de fi exportate în următoarele formate:	Informațiile stocate în baza de date au posibilitatea de fi exportate în următoarele formate:
- format tip DICOM	- format tip DICOM
- format tip MPEG și/sau tip JPEG	- format tip MPEG și/sau tip JPEG
Permite exportul și/sau stocarea informațiilor pe următoarele dispozitive:	Permite exportul și/sau stocarea informațiilor pe următoarele dispozitive:
- USB	- USB
- CD-R	- CD-R
- DVD-R	- DVD-R
POST-PROCESAREA IMAGINII	POST-PROCESAREA IMAGINII
Oferă posibilitatea afișării volumelor achiziționate în următoarele moduri:	Oferă posibilitatea afișării volumelor achiziționate în următoarele moduri:
- singular	- singular
- imagine duală (Planul A/3D)	- imagine duală (Planul A/3D)
CONECTIVITATE ȘI TRANSFER DE DATE	CONECTIVITATE ȘI TRANSFER DE DATE
Ecograful permite conectarea la rețea prin cablu cu conector de tipul RJ45	Ecograful permite conectarea la rețea prin cablu cu conector de tipul RJ45
Dispune de soft ce permite comunicare DICOM	Dispune de soft ce permite comunicare DICOM
B) CONFIGURATIE DE LIVRARE:	B) CONFIGURATIE DE LIVRARE:
B.1) Consola ecografică multidisciplinară îndeplinește toate cerințele de la punctul A)	B.1) Consola ecografică multidisciplinară îndeplinește toate cerințele de la punctul A) - da
B.2) Traductori:	B.2) Traductori:
1 bucată traductor de tip convex pentru aplicații abdominale, obstetrice-ginecologice, pediatrie, urologice, vasculare ce prezintă următoarele caracteristici:	1 bucată traductor de tip convex pentru aplicații abdominale, obstetrice-ginecologice, pediatrie, urologice, vasculare ce prezintă următoarele caracteristici: inclus
- banda de frecvențe de lucru acoperă minim intervalul: 1 - 5	- banda de frecvențe de lucru acoperă minim intervalul: 1 - 5

MHz	MHz
1 bucată traductor de tip endo-cavitar pentru aplicații pediatrice ce prezintă următoarele caracteristici:	1 bucată traductor de tip endo-cavitar pentru aplicații pediatrice ce prezintă următoarele caracteristici: inclus
- banda de frecvențe de lucru acoperă minim intervalul: 3 - 11 MHz	- banda de frecvențe de lucru acoperă minim intervalul: 3 - 11 MHz
- câmp vizual de peste 123°	- câmp vizual de peste 123°
- tehnologie cu peste 125 cristale	- tehnologie cu peste 125 cristale
1 bucată traductor de tip liniară pentru aplicații vasculare, părți moi, pediatrice cu următoarele caracteristici:	1 bucată traductor de tip liniară pentru aplicații vasculare, părți moi, pediatrice cu următoarele caracteristici: inclus
- banda de frecvențe de lucru acoperă minim intervalul: 2 - 8 MHz	- banda de frecvențe de lucru acoperă minim intervalul: 2 - 8 MHz
- câmp vizual de peste 40 mm	- câmp vizual de peste 40 mm
B.3) PERIFERICE SI ACCESORII	B.3) PERIFERICE SI ACCESORII
Printer termic alb-negru	Printer termic alb-negru – da, inclus
C) CONFORMANȚĂ DE SIGURANȚĂ	C) CONFORMANȚĂ DE SIGURANȚĂ
Echipamentul respecta următoarele standarde de siguranță:	Echipamentul respecta următoarele standarde de siguranță:
IEC 60601-1	IEC 60601-1
IEC 60601-1-2	IEC 60601-1-2
ISO 10993-1	ISO 10993-1
D) GARANȚIE ȘI CONDIȚII DE SERVICE	D) GARANȚIE ȘI CONDIȚII DE SERVICE
Garantie - 36 luni pentru consola.	Garantie - 36 luni pentru consola. Garanția pentru sonde 12 luni. Garanția începe din data instalării/
Timp de răspuns la solicitare în perioada de garanție cel mult 48 ore la sediul beneficiarului / locația de instalare	Timp de răspuns la solicitare în perioada de garanție cel mult 48 ore la sediul beneficiarului / locația de instalare
Timp de răspuns la solicitare în perioada de garanție cel mult 72 ore la sediul beneficiarului / locația de instalare	Timp de răspuns la solicitare în perioada de garanție cel mult 72 ore la sediul beneficiarului / locația de instalare
E) SERVICII CONEXE	E) SERVICII CONEXE
Transportul, instalarea, punerea în funcțiune și instruirea personalului se realizează cu personal specializat, cad în sarcina furnizorului și nu implică costuri suplimentare pentru beneficiar fiind incluse în oferta financiară	Transportul, instalarea, punerea în funcțiune și instruirea personalului se realizează cu personal specializat, cad în sarcina furnizorului și nu implică costuri suplimentare pentru beneficiar fiind incluse în oferta financiară
Instalare și punere în funcțiune de către personal autorizat și instruit de producător	Instalare și punere în funcțiune de către personal autorizat și instruit de producător
Instruire personal medical și tehnic la sediul beneficiarului în locația de instalare	Instruire personal medical și tehnic la sediul beneficiarului în locația de instalare
F) TERMEN DE LIVRARE	F) TERMEN DE LIVRARE
45 de zile de la primirea comenzii	45 de zile de la primirea comenzii



Specificație completată

Sistem videoendoscopic pentru video gastroscopie, Model: EPK-3000 + EG-2790K, Producator: Pentax Medical, Tara: Japonia

Sistem videoendoscopic pentru video gastroscopie				
Parametrul			Specificația	Specificație completată
Videoprocessor		Iluminare	auto	DA auto
		Balans de alb	auto	DA auto și la necitate în regim manual
		Acuitate	DA	da
		Videocompensare	DA	da
		Ajustarea culorilor	DA	da
		Zoom Electronic	DA	da
		Suporta tehnologia cromosopia digitală în 3 nivele	DA	da tehnologie i-Scan 1, 2 și 3
		Protocol de amplificarea adaugator pentru fiecare regim de cromosopie digitala.	DA	da este prezind adaugator pentru fiecare regim i-Scan inca 3 nivele de amplificare SE, CE, TE.
		Inclus posibilitatea de transfer a imaginilor direct pe USB sau HDD Extern	DA	DA
		Programa/soft de achizitie si transmitere a imaginilor pe calculator	DA	DA - inclus
		Inscrierea pacientilor in baza interna	DA	DA
		Programarea protocolului pentru fiecare utilizator	DA	DA
		Afisarea datelor video fibrei atasate la procesor la necesitatea utilizatorului.	DA	DA
	Control	Tastatura Alfa numerica	DA	DA
		Butoane cu membrana de protectie	DA	DA
Sursa de lumină	Ieșiri	RGB	1	DA
		Y/C, VGA	≥1	DA
		Digital (DVI, HD-SDI, S-Video, Coaxial)	da	DA DVI-D
		Rezolutia de iesire a imaginii	1920-1080 pix	DA
		Tip	integrată cu procesorul	DA
		Tip lampă	Xenon/Led	DA Xenon
		Timpe de viață lampă	≥500 h	DA 500 h
		Putere lampă	≥ 150 W	DA 150 W
Periferice disponibile	Display medical	Contor lampă	da	DA
		Mod standby	da	DA
		Lampă de rezervă	da	DA integrată
	Lampa de rezervă integrata in video procesor tip		LED	DA LED
			≥ 24 inci	DA medical 24 inch
	Suport pe roțile		da	DA

Sistem de furnizare a aerului/apăi			minim 3 regimuri de lucru	DA
			volumul vasului pentru apă minim 250 ml	DA
Sistem de aspirație	Tip		Separat de procesor	DA
	Volumul rezervorului		1,4-1,8 litri	DA 2 litri
	Vid		-da	DA
	Dirijarea nivelului de aspirare		-în trepte	DA
Accesorii:		Sursa de lumină-	1 unit.	DA - 1 unit
		Pompă –	inclusă	DA
			0,3- 0,6 Pa	DA
		Piesă bucală-	1 unit.	DA - 1 unit
		Tester manual-	1 unit.	DA - 1 unit
		Aspirator endoscopic-	≥0.85 bar	DA
		Vas de rezervă pentru aspirator-	≥ 1,5 l, 1 unit.	DA 2 l.
		Filtre pentru aspirator-	5 unit.	DA - 5 unit
		Monitor –	1 unit.	DA 24 inch
		Trolu-	1 unit.	DA
		Polițe reglabile la înălțime-	4 unit.	DA
				MODEL: EG-2790K
Videogastroscoop	Tip		HD/HD Full	DA
	Tubul de inserție	Lungime totală	≥ 1300 mm	DA 1373 mm
		Lungime de lucru	≥ 1000 mm	DA 1050 mm
		Diametrul exterior	≤ 9.1 mm	DA 9.0 mm
		Marcaj de lungime	da	DA
	Canal de lucru	Numărul de canale	≥1	DA 1
		Diametrul	nu mai mic de 2,8 mm	DA 2,8 mm
	Optica	Unghiul câmpului vizual	≥ 140 grade	DA 140 grade
		Înclinația câmpului vizual	0 grade	DA 0 grade
		Adâncimea câmpului vizual	4-100 mm	DA 4-100 mm
	Tipul și unghiurile de	Sus/jos	210/120 grade	DA 210/120 grade
		Stînga/dreapta	120/120 grade	DA 120/120 grade
	Spălarea obiectivului		da	DA
	Metode de sterilizare	Chimic		DA
		Etilen oxid opțional		DA
		Posibilitatea de a se efectua multiple proceduri de sterilizare		DA
	Programarea butoanelor		DA	DA

Manufacturer's Authorization

Date: **02.04.2019**

Procurement number: **21006092**

To: **"IMSP SR Falesti"**

WHEREAS,

We **GE Medical Systems (China) Co. Ltd.** a company duly existing under the laws of China, having factories at No. 19, Changjiang Road WuXi National Hi-Tech Development Zone Jiangsu, P.R. China, 214028, with Commercial name of **GE Healthcare**, established and reputable manufacturers of Diagnostic Imaging equipment,

In our capacity as official manufacturers of the **Ultrasound System Versana Premier**,

do hereby authorize **Intermed SRL**, our authorized distributor and service provider in the Republic of Moldova, with registered office at **65, Tighina street, office 618, MD-2001 Chisinau**, to submit a bid for the purpose of which is to provide the following Goods, manufactured by us :

Versana Premier Ultrasound System (1 piece),

and to subsequently negotiate and sign the Contract.

On behalf and for **GE Medical Systems (China) Co, Ltd,**



GE Healthcare

Signed: Veronique Soltani

Name: **Veronique Soltani**

Title: **Tender & Offer Leader – Shared Services Europe**

Dated on **26th** day of March, 2019



GE Medical Systems (China) Co, Ltd
19 Changjiang Road
National Hi-Tech Development Zone
214028 Wuxi City Jiangsu
People's Republic of China

Following the provisions of the medical devices directive 93/42/EEC, Annex II and of the directive 2011/65/EU.

Manufacturer

EU Authorized Representative

GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France

Declare under our sole responsibility that the device:

Versana Premier

Ultrasound system, imaging, general-purpose

Ref: see addendum

GMDN Code: 40761

Classification rule (93/42/EEC Annex IX): 10 Class IIa

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gao Gan

Regulatory Affairs

Gao Gao

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep 30, 2018.

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Stampa circulară de înregistrare a Societății cu R.C. S.R. INTERCOM SRL, județul Iași, orașul Chișinău. Conține IDNO 016900034890 și DCCZ177080 (Rev. 02). Este semnată cu o semnătură roșie.



This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
 - Technical Documentation/DHF Ref./ réf: **DOC2177084/DOC1954045**, of the product to which this declaration relates
 - EC Certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by **TÜV Rheinland LGA Products GmbH** (Notified Body 0197) / Certificate N HD 60116081 0001
 - harmonized standards applied on the product to which this declaration relates
 - EN 60601-1:2006 + A1:2013 Medical electrical equipment - Part 1: General requirements for safety
 - EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility
 - EN 60601-1-6: 2010+ A1:2015 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
 - EN 60601-2-37:2008+A1:2015 Medical electrical equipment - Part 2-37: Requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
 - EN 62366:2008 + A1:2015 Medical devices – Application of usability engineering to medical devices
 - EN 62304:2006 + AC:2008 Medical device software – Software life-cycle processes
 - EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices
 - EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels /labelling
- For the directive 2011/65/EU (RoHS)
 - Technical Documentation/DHF Ref./ réf: **DOC2177084/DOC1954045**, of the product to which this declaration relates
- For the directive 2014/53/EU (Radio Equipment Directive)
 - Technical Documentation/DHF Ref./ réf: **DOC2177084/DOC1954045**, of the product to which this declaration relates
 - harmonized standards applied on the product to which this declaration relates:
 - Health & Safety (Directive 2014/53/EU Art. 3(1)(a)): EN 60601-1-2: 2015; Directive 93/42/EEC; Directive 2014/30/EU; EN 60601-1: 2006/A1:2013
 - EMC (Directive 2014/53/EU Art.3(1)(b)): EN 60601-1-2: 2007 +AC: 2010 Section 6; Directive 93/42/EEC; Directive 2014/35/EU
 - Radio Spectrum (Directive 2014/53/EU Art.3(2)): EN 300 328 v 2.1.1 (2016-11); EN301 893 v 1.8.1 (2015-03) + EN 301 893 V 2.1.1. (clause 4.2.8 only)-as declared in DOC2007709.

Wuxi, 19-Oct-2018

Gao Gan *Gao Gan*
Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep 30, 2018.





ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2177080
Versana Premier configurations- Consoles and options

CONSOLE Name with description	GEHC Part ⁽¹⁾	REF # ⁽²⁾	GEHC Cat # ⁽³⁾
Versana Premier VS	5804137	Versana Premier VS	H48152BA
Versana Premier VS w flex CP	5804138	Versana Premier VS	H48152BB
Versana Premier VA	5804136	Versana Premier VA	H48152BC
Versana Premier VA w 4D	5804139	Versana Premier VA	H48152BE
Options Consoles		GEHC Cat # ⁽³⁾	
VSN Premier DICOM			H48162BA
VSN Premier Follow up tool			H48162BB
VSN Premier LOGIQ VIEW			H48162BC
VSN Premier Easy/Adv 3D			H48162BD
VSN Premier B-flow/color			H48162BE
VSN Premier Contrast			H48162BF
VSN Premier Tricify Uplink			H48162BG
VSN Premier 4D software			H48162BH
VSN Premier VOCAL			H48162BJ
VSN Premier Auto IMT			H48162BK
VSN Premier TVI			H48162BL
VSN Premier AMM			H48162BM
VSN Premier Stress Echo			H48162BN
VSN Premier Auto EF			H48162BP
VSN Premier CWD			H48162BR
VSN Premier Needle rec			H48162BS
VSN Premier Elastography			H48162BT
VSN Premier Breast Care			H48162BW
VSN Premier Thyroid prod			H48162BZ
VSN Premier VA-IQ			H48172BA
4D Hardware option			H48172BW
VSN Premier Gel Warmer			H48182BA
isolation USB for AC printer			H48242BC
Battery			H48772AT
Battery kit			H48192BM
VSN P Battery Install Kit			H48182BD
VSN Premier 4PP HW option			H48182BH
VSN Premier Articular Arm			H48182BJ
paper tray			H48182BF

Notes used in the table :

1. **GEHC Part #** identifies the device(s) in the manufacturer's design, manufacturing and service documentation.
2. **REF #** is usually affixed to the device(s) in the form of a product identification or model on the rating label.
3. **GEHC Cat #** identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

Wuxi, 19-Oct-2018

Gao Gan *Gao Gan*
Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep 30, 2018



Versana Premier – Probes with Accessories

PROBES and Accessories ^[4]	TYPE ^[5]	GEHC Cat # ^[3]
4C-RS Convex array probe	BF	H4000SR
E8C-RS probe	BF	H40402LN
8C-RS Convex array probe	BF	H40402LS
L8-18i-RS	BF	H40462LF
BE9Cs-RS	BF	H40482LN
6S-RS	BF	H45021RP
3Sc-RS Phased Array probe	BF	H45041DL
L6-12-RS Linear Array probe	BF	H48062AC
E8Cs-RS	BF	H48062AF
RAB2-6-RS probe	BF	H48681WR
12L-RS	BF	H40402LY
12S-RS	BF	H44901AB
LK760-RS	BF	H44901AF
RIC5-9A-RS	BF	H48701EJ
4C-RS Biopsy Kit	N/A	E8385NA
L6-12-RS Biopsy Kit	N/A	H40432LC
3Sc-RS Biopsy Kit	N/A	H46222LC
RAB2-6-RS Biopsy Kit	N/A	H48681ML
E8C-RS Biopsy Kit	N/A	E8385MJ
E8C-RS Reusable Biopsy Kit	N/A	H40412LN
BE9CS disposal	N/A	E8387M
BE9CS Reusable	N/A	E8387MA
12L Transverse bracket	N/A	H48392LL
Infinite 12L biopsy kit	N/A	H48392LT
Reusable Biopsy Guide for RIC5-9A-RS	N/A	H46721R
Disposable Biopsy Guide for RIC5-9A-RS	N/A	H48681GF
Disposable Biopsy Guide with Covers for RIC5-9A-RS	N/A	H48691Z

Notes used in the table :

3. GEHC Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.
4. Probes and accessories may carry the CE-mark and, when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE-marked by their manufacturer. GE Medical Systems (China) Co., Ltd. has verified the mutual compatibility of the devices in combination with Versana Premier and included relevant information to users with the Versana Premier instructions for use. This activity was subject to appropriate methods of internal control and inspection.
5. Type identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.

Wuxi, 19-Oct-2018

Gao Gan *Gao Gan*
Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep 30, 2018.





Versana Premier – Accessories

Accessories ^[6]	GEHC Cat # ^[3]
SONY UPD25 Color Printer USA Kit	H48542LZ
SONY UPD25 Color Printer EUP Kit	H48552LA
SONY UPD25 Color Printer CHN Kit	H48542LY
SONY UPD25 Color Printer JPN Kit	H48552LB
SONY UPD25 Color Printer Brazil Kit	H48312AN
BW PRINTER (UP-D898MD)	H48492AZ
UP-D898DC Printer	H48052BG
Versana Premier printer shelf	H48192BF
898 printer paper	H41402LS
UP-D898MD DC Printer OFC	H48192BN
Footswitch MKF 2-MED USB GP26	H41642LS
1-Peadi type footswitch 'Whanam FSU-1000'	H41882LD
USB Stick	H48962LC
1TB mobile USB HDD	H48492AB
Transcend TS8XDVDS-K DVDRW kit with SW	H48192BL
USB ECG Module (IEC)-MFG Germany	H48502AR
USB ECG Module (AHA)-MFG Israel	H41852LK
USB ECG Module (IEC)-MFG Israel	H41852LL
ECG ASSY w/ Chinese Label	H41852LM
wireless Adaptor	H48832AC
Bluetooth Adaptor	H48122BT
SonoStore White Label	H48902AJ
SonoStore Blue Label	H48902AH
EMI Filter	H48242BD

Notes used in the table :

3. **GEHC Cat #** identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.
6. **Accessories** may carry the CE-mark and, when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE-marked by their manufacturer. GE Medical Systems (China) Co., Ltd. has verified the mutual compatibility of the devices in combination with Versana Premier and included relevant information to users with the Versana Premier instructions for use. This activity was subject to appropriate methods of internal control and inspection.

Wuxi, 19-Oct-2018

Gao Gan *Gao Gan*
Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep 30, 2018.



Versana Premier – Vet Consoles and Options

Vet Consoles and Options	GEHC Cat # ⁽³⁾
VSN Premier VS vet console	H48152BG
VSN Premier VS w flex CP vet console	H48152BH
VSN Premier VA vet console	H48152BJ
Vet probe caution label	H48492AW
Vet probe caution label	H48992LR
Versana Premier Vet kits	H48182BE

Notes used in the table :

3. **GEHC Cat #** identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

Wuxi, 19-Oct-2018

Gao Gan *Gao Gan*
Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep.30, 2018.



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

Registration No.: HD 60116081 0001

Report No.: 15094929 004

Manufacturer: GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60110059 0001

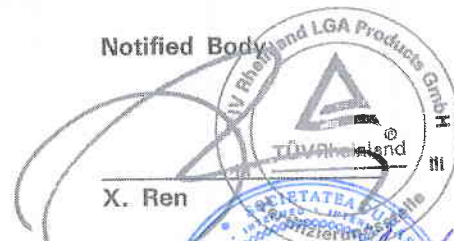
Expiry Date: 2021-05-02

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: 2017-01-03

Date: 2017-01-03

Notified Body



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

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60116081 0001
Report No.: 15094929 004

Manufacturer: GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

Manufacture of Ultrasound Diagnostic Systems

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Storage of Ultrasound Diagnostic Systems

Date: 2017-01-03

Notified Body

X. Ren



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.1

**Attachment to
Certificate**

Registration No.: HD 60116081 0001
Report No.: 15094929 005

Manufacturer: GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Products:

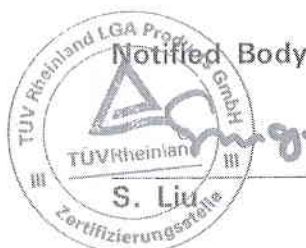
- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Date: 2017-12-20



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China**

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

**Design and Development, 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: 2017-12-20
Certificate Registration No.: SX 60123505 0001
An audit was performed. Report No.: 15094484 005
This Certificate is valid until: 2020-06-30

Certification Body

DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-12-20



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 60123505 0001
Report No.: 15094484 005

Organization: GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Scope:

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

**Manufacture and Distribution of Ultrasound Diagnostic
Systems**

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

**Storage and Distribution of Ultrasound Diagnostic Systems
and Probes, Anesthesia Devices, Bone Densitometry Systems,
ECG Module**

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2017-12-20





Versana Premier™

Care with Confidence



Premier

Productive.
Sound designed for peace of mind.

ound system can help you deliver high-quality, personalized care, er busy day. This innovative system is well suited for general practice nters, community health clinics, and other facilities offering basic o cover abdominal, OB/GYN, cardiac, urology, vascular and

clinical features let you provide quick and comfortable exams, iagnose a broad range of conditions.

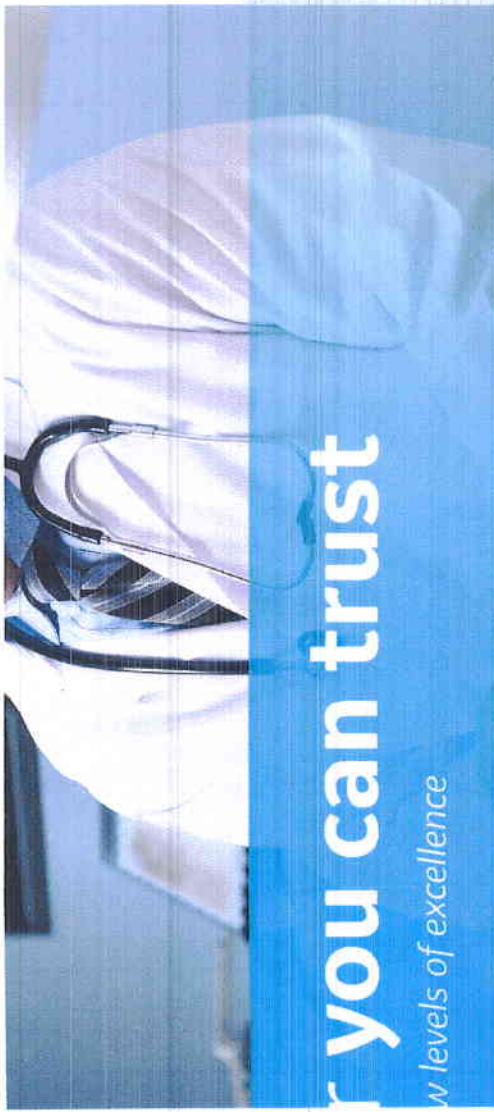
activity tools

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support

ana users





...er you can trust

...w levels of excellence

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nding imaging power and clarity to boost diagnostic confidence. It helps you see
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Sensitive B-Flow™ and B-Flow color imaging to analyze blood flow,
diagnose vessel-wall irregularities and stenosis, and more.



- Simple maintenance; easy troubleshooting and repair
- InSite™ service technology† for fast remote diagnostics and repairs



+ Decades of GE Healthcare heritage at your servi

Invest in Versana Premier and benefit from vast GE ultrasound expe
with you, your practice, and your patients in mind to meet your clini
connectivity needs.

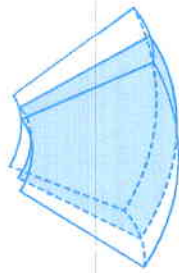


Simple to use

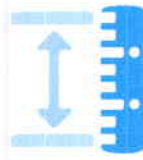
Applications help you diagnose a wide spectrum of patient conditions. Intuitive workflow. The system boots up quickly and operates quietly. It is compact to fit small between rooms.



Whizz dynamic image tuning continuously optimizes the image as you scan, even as you move from one organ or area to another



Use **3D volume** imaging for rich anatomical views



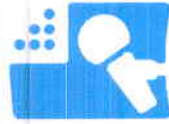
Take **automated measurements** of bladder volume, cysts or masses, IUT thickness, fetal characteristics and more



Use **battery power** to move the system from room to room without powering down



Network options let use the cloud¹ to share images with for consultation²



Overlay **voice comments** on images for playback when reviewing exams

Touch-panel



Versana Premier. Powerful. Versatile. Productive.

+ Sharp stay a

- Scan Coe illustrati
- My Traini care, seti
- Web-bas
- Local fac





An opportunity for growth

Ultrasound to serve you well today and set your course for the future.

+ Experience the strength of the GE Healthcare family

Your support team is fully trained & GE Healthcare qualified, deeply experienced, and close by.

- Expert support during and after purchase
- In-depth product instruction
- Remote or on-site technical, clinical and network support

+ Customized solutions and path to growth

Help your practice grow with Versana Premier. You can select a basic package, with the option to add more probes and software. Or let GE experts help select another system to suit your needs.

+ Versana Club: Learn. Network. Share.

The Versana Club gives you access to member resources members that can help expand your ultrasound knowledge and improve your practice. It's a place to share images with your peers from around the world.

You'll also enjoy:

- Educational offerings
- Web-based video tutorials
- Information on Versana family service solutions and products
- Up-to-date content on ultrasound and patient care
- Notices of regional ultrasound events and other news
- Access to the broader family of GE ultrasound user clubs



Versana Premier. Care with Confidence.

Powerful. Versatile. Productive. World-class ultrasound designed for peace-of-mind.

[†] Local educational offerings may vary according to regions. Please check with your local GE representative.

^{*} Option may not be available in all countries.

[‡] Requires internet connection; may not be available in all countries.

[‡] Image sharing to mobile devices via Bluetooth available in some countries

[‡] Financing options vary from country to country. Please check with your local GE representative.

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Imagination at work

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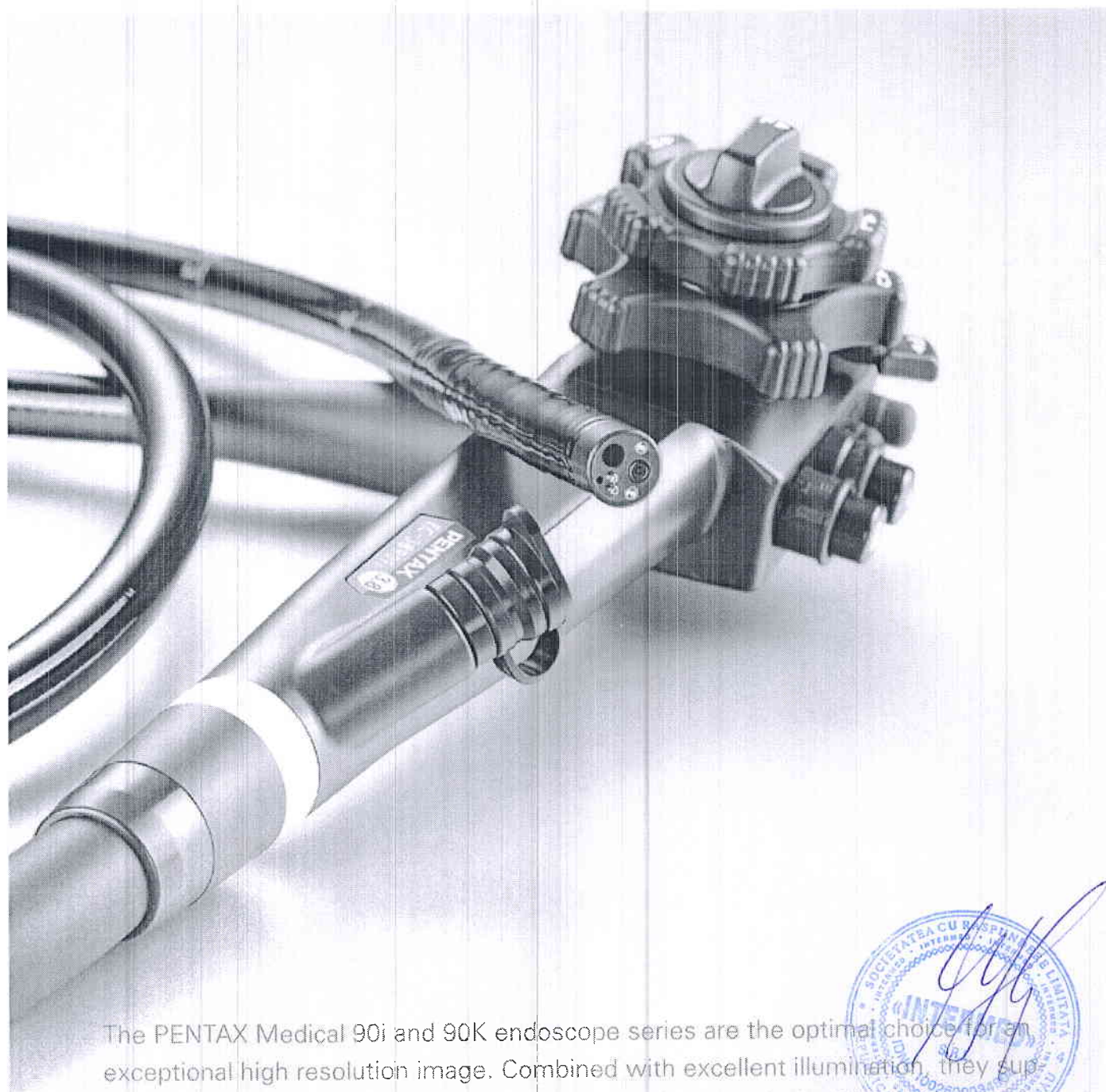


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The redefinition of High-Definition.



The PENTAX Medical 90i and 90K endoscope series are the optimal choice for an exceptional high resolution image. Combined with excellent illumination, they support better orientation and detection in endoscopic procedures. With the 90i endoscope series you can fully experience HD+ images during routine examinations.



A wide range of High-Definition HD+ endoscopes.

90i and 90K endoscope series

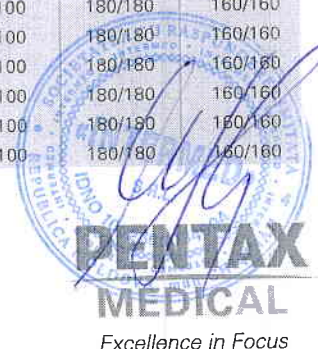
- Excellent illumination for better orientation
- Megapixel CCD for an excellent image quality
- Graduated flexibility (GDF) to facilitate the examination

Product	Insertion tube [ø mm]	Instrument channel [ø mm]	Working length [mm]	Total length [mm]	Angle of view [mm]	Focal range [mm]	Tip deflection up/down [°]	Tip deflection right/left [°]
Gastrosopes 90i								
EG-2990i	9.8	2.8	1,050	1,373	140	5-100	210/120	120/120
EG-2990Zi	9.8	2.8	1,050	1,060	140	5-100	210/120	120/120
Gastrosopes 90K								
EG-1690K	5.4	2.0	1,100	1,423	120	4-100	210/120	120/120
EG-2490K	8.0	2.4	1,050	1,373	140	4-100	210/120	120/120
EG-2790K	9.0	2.8	1,050	1,373	140	4-100	210/120	120/120
EG-2990K	9.8	2.8	1,050	1,373	140	4-100	210/120	120/120
EG-3490K	11.6	3.8	1,050	1,373	140	4-100	210/120	120/120
EG-3890TK	12.8	3.8/2.8	1,050	1,383	140	4-100	180/120	120/120
Duodenoscope								
ED-3490TK	11.6	4.2	1,250	1,573	100 (retro 10)	4-60	120/90	105/90
Enteroscope								
VSF-2990i	9.8	2.8	2,200	2,523	140	3-100	180/180	160/160
Colonoscopes 90i								
EC-2990Fi	9.8	2.8	1,500	1,823	140	3-100	180/180	160/160
EC-2990Li	9.8	2.8	1,700	2,023	140	3-100	180/180	160/160
EC-2990Mi	9.8	2.8	1,300	1,623	140	3-100	180/180	160/160
EC-3490Fi	11.6	3.2	1,500	1,823	140	4-100	180/180	160/160
EC-3490Li	11.6	3.2	1,700	2,023	140	4-100	180/180	160/160
EC-3490Tmi	11.6	3.2	1,300	1,623	140	3-100	210/180	160/160
EC-3490TFi	11.6	3.2	1,500	1,823	140	3-100	210/180	160/160
EC-3490TLi	11.6	3.2	1,700	2,023	140	3-100	210/180	160/160
EC-3890Mi	13.2	3.8	1,300	1,623	140	4-100	180/180	160/160
EC-3890Mi2*	13.2	3.8	1,300	1,623	140	4-100	180/180	160/160
EC-3890Fi	13.2	3.8	1,500	1,823	140	4-100	180/180	160/160
EC-3890Fi2*	13.2	3.8	1,500	1,823	140	4-100	180/180	160/160
EC-3890Li	13.2	3.8	1,700	2,023	140	4-100	180/180	160/160
EC-3890FZi	13.2	3.8	1,500	1,300	140	4-100	180/180	160/160
EC-3890LZi	13.2	3.8	1,700	1,300	140	4-100	180/180	160/160
EC-3890MZi	13.2	3.8	1,300	1,300	140	4-100	180/180	160/160
Colonoscopes 90K								
EC-3490FK	11.6	3.8	1,500	1,823	140	3-100	180/180	160/160
EC-3490LK	11.6	3.8	1,700	2,023	140	3-100	180/180	160/160
EC-3890MK	13.2	4.2	1,300	1,623	140	3-100	180/180	160/160
EC-3890MK2*	13.2	4.2	1,300	1,623	140	3-100	180/180	160/160
EC-3890FK	13.2	4.2	1,500	1,823	140	3-100	180/180	160/160
EC-3890FK2*	13.2	4.2	1,500	1,823	140	3-100	180/180	160/160
EC-3890LK	13.2	4.2	1,700	2,023	140	3-100	180/180	160/160
EC-3890TFK	13.2	3.8/2.8	1,500	1,823	140	3-100	180/180	160/160
EC-3890TLK	13.2	3.8/2.8	1,700	2,023	140	3-100	180/180	160/160

*insertion tube with increased rigidity in comparison with standard equipment

PENTAX Europe GmbH

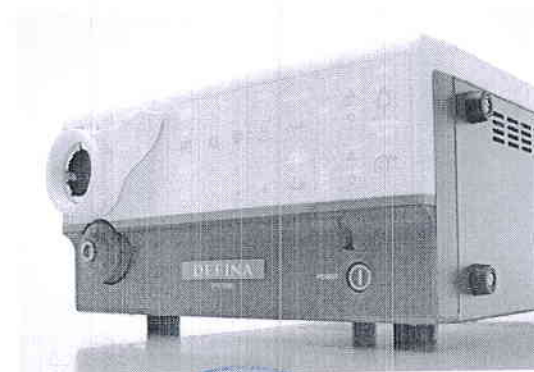
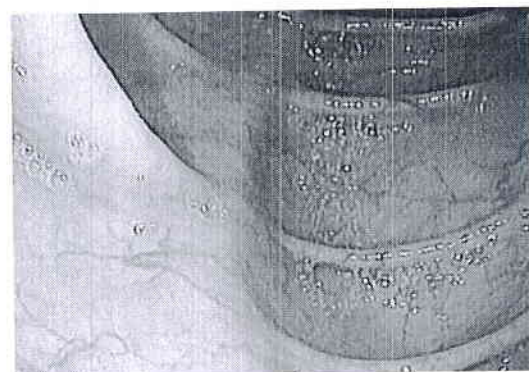
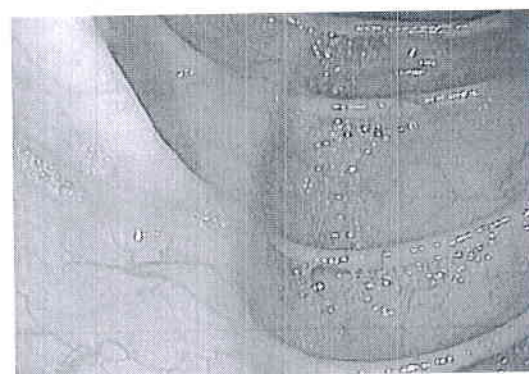
Julius-Vosseler-Straße 104 · 22527 Hamburg · Germany
 *Tel.: +49 40 / 5 61 92 - 0 · Fax: +49 40 / 5 60 42 13
 E-mail: medical@pentax.de · www.pentaxmedical.com

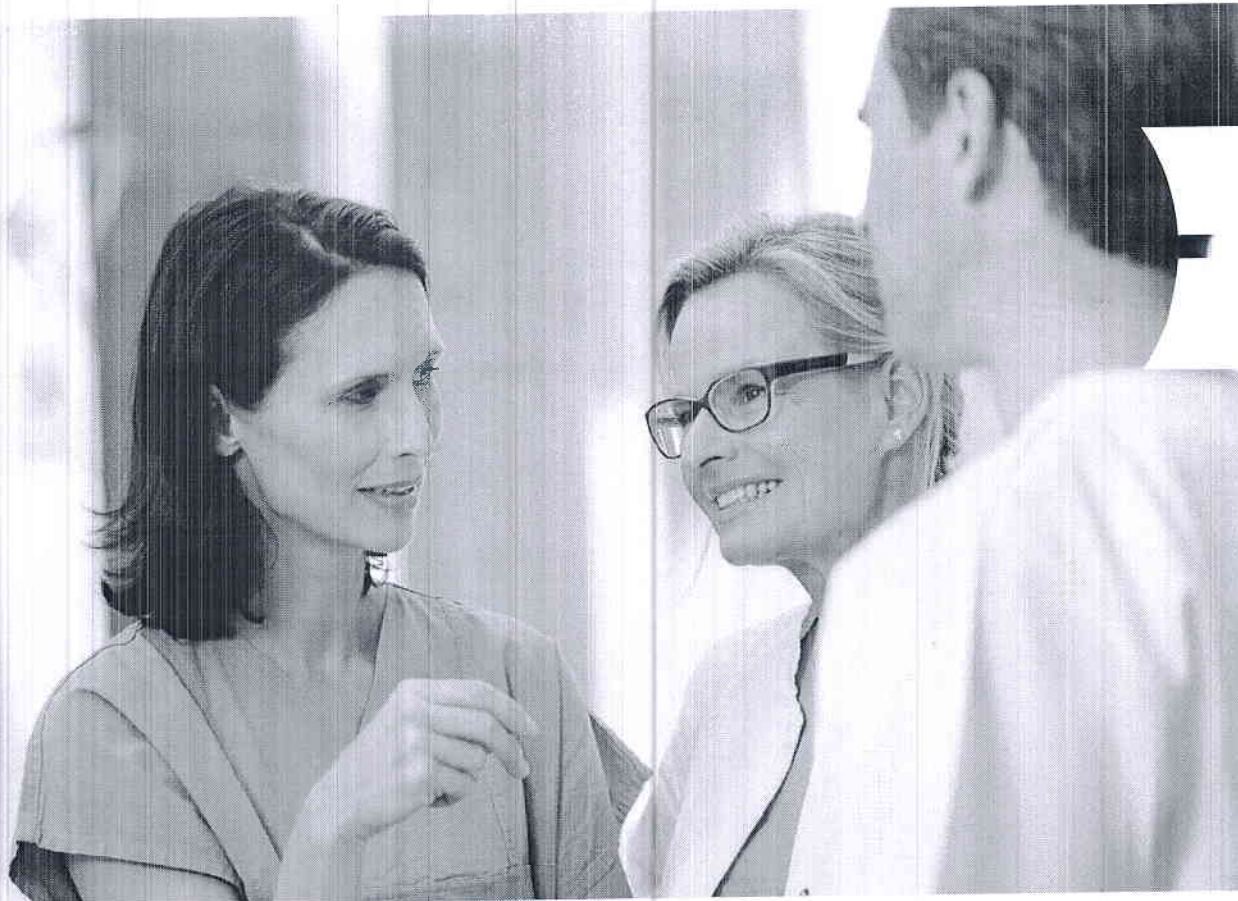


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DEFINA Solution EPK-3000 Video Processor

*Enter the world of HD endoscopy with flexible solutions
for your clinical practice.*





HD endoscopy technology that offers you a choice.

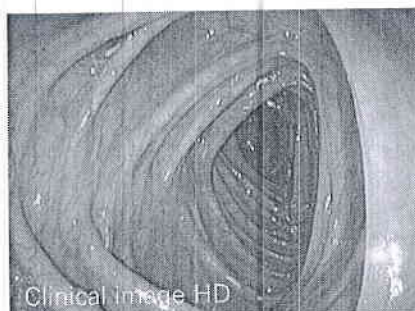
The High-Definition DEFINA EPK-3000 video processor provides a flexible platform that allows you to select the level of technology that meets your clinical and financial needs.

The DEFINA HD solution offers the same high-quality HD imaging to all specialties, whether gastrointestinal, EUS, respiratory or ENT. In addition, you have the choice of whether to include our i-scan image enhancement software, both now and in the future.

If you are planning to upgrade from standard definition to High-Definition endoscopy with a choice to explore the benefits of image enhancement technology, the DEFINA EPK-3000 video processor offers the flexibility to create the optimal endoscopy system for your facility.



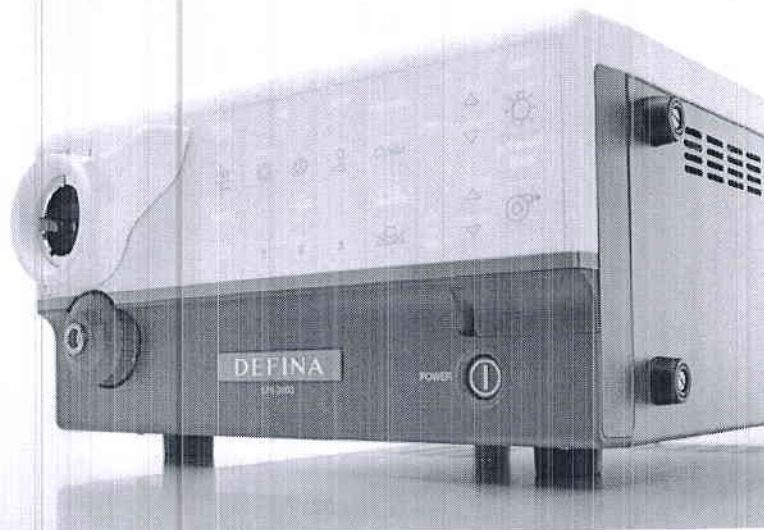
Clinical image SD



Clinical image HD



DEFINA – optimize your daily clinical practice with the High-Definition EPK-3000 video processor.



The High-Definition DEFINA system offers a high-quality HD image to support the day-to-day diagnostic and therapeutic needs of a modern endoscopic facility.

1

Excellent visualization

Brilliant, **High-Definition** images with **xenon light** for a clear and more detailed visualization of the mucosal structures. Dynamic range expansion provides excellent illumination to improve **far-field visualization**.

2

Flexible platform

Designed as a multi-purpose platform, DEFINA supports varying specialties such as GI, EUS, Pulmonology and ENT, optimizing a hospital's investment and workflow.

3

Upgradeable capabilities

The High Definition image can be enhanced with **i-scan technology** to support detection, demarcation, and characterization.



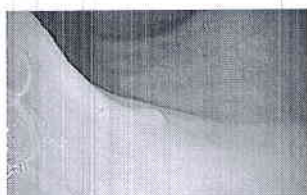
Excellent visualization

High-Definition image

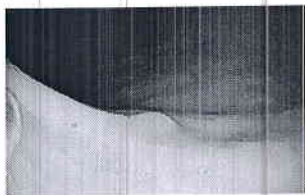
An HD image with excellent illumination of xenon light ensures better visualization during daily procedures.

ESGE suggests the routine use of High-Definition white-light endoscopy systems for detecting colorectal neoplasia in average risk populations.¹¹

The High-Definition DEFINA system has the potential to merge sharp and clear image quality with i-scan technology for fast detection and precise demarcation to support characterization and patient treatment.



i-scan 1 mode



i-scan 2 mode



i-scan 3 mode

Dynamic range expansion

Dynamic range expansion is a software enhancement that provides improved far-field visualization. When trying to image a distal lumen and a proximal view is impossible, this feature is invaluable.



D-Range OFF



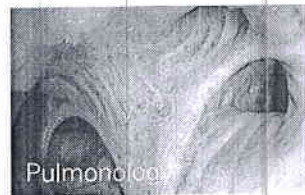
D-Range ON

Flexible platform

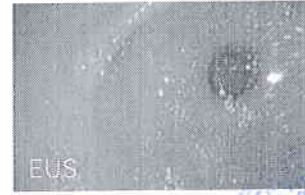
Designed as a multi-purpose platform, DEFINA supports varied specialties such as GI, EUS, Pulmonology, and ENT, for the optimization of a hospital's investment and workflow.



Larynx in i-scan 1 mode.
Image obtained with DEFINA and with a J10 Naso-Pharyngo-Laryngoscope video endoscope



Right upper lobe in i-scan 2 mode. Image obtained with DEFINA and a J10 video bronchoscope.



Gastric Antrum in i-scan 1 mode.
Image obtained with DEFINA and a 70K ultrasound video endoscope.



Upgradeable capabilities

A system that offers a choice

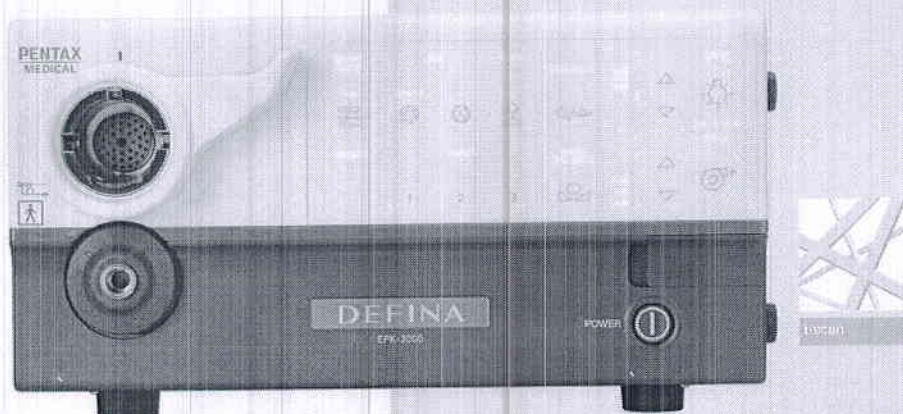
The DEFINA solution gives you the choice of a light version or the full version with i-scan. The light version of DEFINA can be always upgraded with a separate kit, available to enhance your diagnostic capabilities with i-scan.

DEFINA Solutions

DEFINA EPK-3000

Light version with
upgradeable capabilities

Full version with i-scan



i-scan UPGRADING KIT

This is available at any time.

With its user-friendly interface, compact size, and ease-of-operation, this is the economically efficient endoscopy diagnostic solution for a smaller budget: the light version of DEFINA.

With its excellent price performance ratio, the full version of DEFINA with i-scan is the ideal video processor with which to enter the world of High-Definition and i-scan for an enhanced diagnosis.

Upgrading made easy

We are pleased to offer you an easy and fast way to upgrade your DEFINA system. Once you have made the decision to further enhance your optical diagnosis with i-scan, please contact your PENTAX Medical representative for ordering information on the i-scan upgrading kit.



Advanced Solutions

The DEFINA EPK-3000 is a versatile endoscopic solution, offering the unique ability to upgrade the system from the light version of DEFINA to DEFINA with i-scan. The upgrade allows you to enter the world of High-Definition enhanced with i-scan to ensure optimized diagnosis results.

Enhance your clinical outcomes with i-scan

i-scan is a digital image enhancement endoscopy technology and a virtual endoscopy tool. Easily operated with just the touch of a button, it offers rapid imaging results and real-time processing. Based on proven clinical studies and feedback from key industry opinion leaders, the HD imaging combined with i-scan technology offers significant advantages: it improves the ability to detect, characterize, and demarcate suspicious lesions in the lower and upper GI, and helps to provide targeted intervention at an early stage.

Tailor your i-scan setting to your clinical needs

SE enhances the light/dark contrast, which in turn enhances the structure through recognition of the edges.



i-scan 1 Surface Enhancement (SE) enhances the mucosa structure in natural color tones to support **detection**, especially of flat lesions, by highlighting abnormalities.

TE alternates discrete parts of light spectrum components (red, green, blue) of a normal image and enhances minute mucosal structures and subtle changes in color.



i-scan 2 Tone Enhancement (TE) enhances the changes of vascular and mucosal structure with a color tone change, to support pattern **characterization**.

CE adds the color blue in relatively dark areas (to the edges) by obtaining luminance intensity.



i-scan 3 Contrast Enhancement (CE) enhances the depressed areas and differences in structure through colored presentation of low density areas, to support **demarcation**.

i-scan supporting the diagnostic pathway



i-scan 1 (SE) – detection



i-scan 2 (TE) – characterization



i-scan 3 (CE) – demarcation

Handwritten signature and a circular blue stamp with text: "CHINA MEDICAL EQUIPMENT & SUPPLY CO., LTD." and "BEIJING, CHINA".

Technology with proven results

Clinical studies have already shown that i-scan technology can significantly improve:

- **Adenoma detection rate (ADR)**, especially of **colon polyps located in the right colon**, namely the **flat and depressed adenoma and serrated polyps**.^(1, 2)
- i-scan supports better prediction of **inflammatory bowel disease (IBD)**.⁽³⁾
- In **gastroesophageal reflux disease (GERD)** i-scan is able to detect minimal changes and accurately characterize the identified lesions (inflammation vs. neoplasia) during ongoing endoscopy.⁽⁴⁾
- In **Barrets' oesophagus**, i-scan improves dysplasia detection, which is superior to random biopsies.⁽⁵⁾

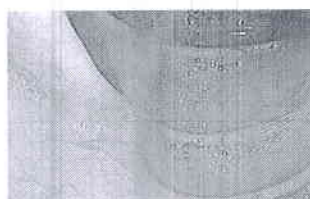
⁽¹⁾ Neumann *et al.* Virtual Chromoendoscopy With i-SCAN Improves the Detection of Right Sided Colon Adenomas in Comparison to High-Definition White Light Endoscopy. *Gastrointestinal Endoscopy*. May 2013, Volume 77, Issue 5, Supplement, Page AS552.

⁽²⁾ Testoni *et al.* High-Definition colonoscopy with i-Scan: Better diagnosis for small polyps and flat adenomas. *World J Gastroenterol* 2012 October 7; 18(37): 5231-5239.

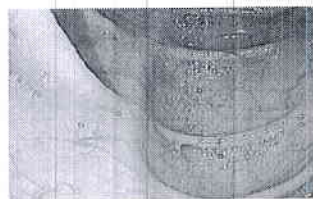
⁽³⁾ Iacucci *et al.* iSCAN-High-Definition colonoscopy correlates with white light endoscopy and histology assessment in mucosal healing for ulcerative colitis. *Journal of Crohns and Colitis* February 2013; 7:S53-S54.

⁽⁴⁾ Kim *et al.* Efficacy of i-scan Endoscopy in the Diagnosis of Gastroesophageal Reflux Disease with Minimal Change. *Clin Endosc* 2011;44:27-32.

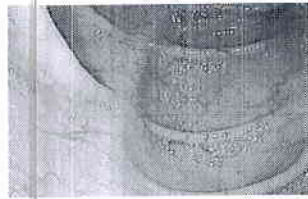
⁽⁵⁾ Hoffman *et al.* Acetic acid compared with i-scan imaging for detecting Barrett's esophagus: a randomized, comparative trial. *Gastrointest Endosc*. 2014 Jan;79(1):46-54.



i-scan 1 mode



i-scan 2 mode



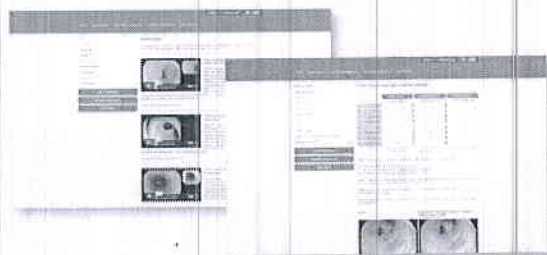
i-scan 3 mode

i-scan website

Enter the i-scan world and exchange and expand your i-scan knowledge

Enroll in the i-scan platform and...

- get exclusive i-scan content
- attend i-scan webinars presented by experts
- expand your i-scan learning with online training modules
- receive i-scan certification by putting your i-scan knowledge to the test
- choose your language: English, French, German, Italian, Russian or Spanish



www.i-scanimaging.com



Knowledge is power

i-scan certification

The i-scan certification has the aim to empower the clinical team to fully utilize i-scan in routine practice, fully leveraging on its proven benefits. With every upgraded DEFINA EPK-3000 video processor installation, your clinical team gets access to a comprehensive i-scan training platform, comprising self-training modules on i-scan classifications, tutorial videos and webinars. This platform stores a record of your progress and automatically informs you when new learning content is available.

After completion of the i-scan online training module, an i-scan certification will be issued by the i-scan task force to attest your i-scan knowledge.

How do I get i-scan certification?

Step 1

Enroll in the PENTAX
Medical customer portal



www.mypentaxmedical.eu

Step 2

Navigate to the i-scan
certification tab



i-scan CERT

Step 3

Complete the activities

Finish the
self-education
classification
module

+

Learn
from a
webinar

=

i-scan
certificate
module 1

✓ Pass the test

✓ Pass the test

Training for Excellence

This PENTAX Medical initiative is designed to assist endoscopic professionals in improving the quality of endoscopy. Leverage on the Training for Excellence programs provided by PENTAX Medical to maximize the i-scan benefits and best practices in endoscopy.

www.training-for-excellence.eu



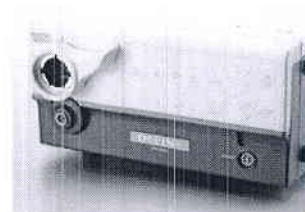
A range that meets all needs

The 90k and Kp endoscope series

PENTAX Medical offers two endoscope series and a range of models to ensure that all types of medical facilities and their patients can benefit from the latest HD endoscopy technology.

DEFINA EPK-3000 Video Processor

HD video output	DVI-D (1920 x 1080i)
SD video output	RGB, Y/C, composite
User interface	Control panel, keyboard
i-scan virtual chromoendoscopy	Quick access via i-scan keys 1, 2, 3
Light source	150W Xenon
Dimensions (W x H x D / weight)	350 x 180 x 485 mm / 13.0 kg
Image Enhancement	Digital Image Enhancement: i-scan (SE, TE, CE) Enhances the endoscopic view of mucosal surface and vessel patterns.
Dynamic Range Expansion	Off, Low, Med, High Adjustment for optimising image brightness in darker areas of an image
Freeze Scan	Off, Low, Med, High Selects the sharpest image from a series of images temporarily stored in the processor memory, whenever an image is frozen.
Digital Zoom	Magnification options: Off, 1.2x, 1.5x, 2.0x



90K Series endoscopes

Models	Insertion tube [ø mm]	Instrument channel [ø mm]	Working length (mm)	Total length (mm)	Field of view (degrees)	Focal range (mm)	Angulation Up / Down	Angulation Right / Left
90K series gastroscopes								
EG-2490K	8	2.4	1050	1373	140	4 - 100	210 - 120	120 - 120
EG-2790K	9	2.8	1050	1373	140	4 - 100	210 - 120	120 - 120
EG-2990K	9.8	2.8	1050	1373	140	4 - 100	210 - 120	120 - 120
EG-3490K	11.6	3.8	1050	1373	140	4 - 100	210 / 120	120 / 120
90K series colonoscopes								
EC-3490LK	11.6	3.8	1700	2023	140	3 - 100	180 / 180	160 / 160
EC-3490FK	11.6	3.8	1500	1823	140	3 - 100	180 / 180	160 / 160
EC-3890LK	13.2	4.2	1700	2023	140	3 - 100	180 / 180	160 / 160
EC-3890FK	13.2	4.2	1500	1823	140	3 - 100	180 / 180	160 / 160
K10 transnasal gastroscop								
EG16-K10	5.4	2.0	1100	1416	140	4 - 100	210 / 120	120 / 120



Kp Series endoscopes

Models	Insertion tube [ø mm]	Instrument channel [ø mm]	Working length (mm)	Total length (mm)	Field of view (degrees)	Focal range (mm)	Angulation Up / Down	Angulation Right / Left
Kp series gastroscop								
EG-290Kp	9.8	2.8	1050	1373	140	5 - 100	210/120	120/120
Kp series colonoscopes								
EC-380LKp	13.2	3.8	1700	2023	140	3 - 100	180 - 180	160 - 160
EC-380FKp	13.2	3.8	1500	1823	140	3 - 100	180 - 180	160 - 160



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Shinjuku-ku
Tokyo 160-00231





Product Service

CERTIFICATE

No. Q1N 17 08 68357 024

Holder of Certificate: **HOYA Corporation**
PENTAX
MEDICAL
 6-10-1 Nishi-shinjuku
 Shinjuku-ku
 Tokyo
 160-0023 JAPAN



Certification Mark:



Scope of Certificate: **Design and Development, Production,
 Distribution and Servicing of
 Medical Endoscopes and Related Products**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: JAQ235030361

Valid from: 2018-02-01
 Valid until: 2021-01-31



Date, 2018-01-26

I. Preiß
 Stefan Preiß

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany





Product Service

CERTIFICATE**No. Q1N 17 08 68357 024****Applied Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

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Instrument SBU Japan Sales Headquarters
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JAPAN

HOYA Corporation PENTAX Lifecare Division
Production Technology Center / Ogawa Factory
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355-0316 JAPAN

HOYA Corporation PENTAX Miyagi Factory
30-2 Okada, Aza-Shimomiyano, Tsukidate, Kurihara-shi,
Miyagi, 987-2203 JAPAN

HOYA Corporation PENTAX Yamagata Factory
4-1 Hinode-cho, Nagai-shi, Yamagata, 993-0012 JAPAN



平成 28 年 6 月 15 日

関係各位

宣 言 書

私どもHOYA株式会社、東京都新宿区西新宿六丁目10番1号は、添付の下記文書が書類原本の複製であることを証明致します。

「EU DECLARATION OF CONFORMITY ER-QL-193」

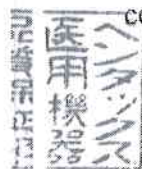
HOYA 株式会社
PENTAX ライフケア事業部
品質保証部 部長
丸澤 宏

June 15, 2016

To whom it may concern

STATEMENT

We, HOYA Corporation (6-10-1, Nishi-Shinjuku, Shinjuku-ku, Tokyo 160-0023, Japan), hereby certify that attached document listed above is the copy of the original document.



Hiroshi Marusawa
General Manager
Global Quality Assurance and Regulatory Affairs
HOYA Corporation PENTAX Lifecare Division



PENTAX
MEDICAL

EU DECLARATION OF CONFORMITY

We ; HOYA Corporation

6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo

160-0023, Japan

declare under our sole responsibility that PENTAX or PENTAX Medical brand product:

Product Category : Endoscopes, video processors and accessories
Model Name : See attached

Meets;

- 1) the conformity assessment procedure in Annex II in accordance with the provisions of Medical Devices Directive 93/42/EEC. The classification and rules applied to each model are described in the attachment.

This declaration is based on EC quality system approved by

TÜV SÜD Product Service GmbH (No.0123), Ridlerstraße 65, 80339 München, Germany

- 2) the provisions of RoHS Directive 2011/65/EU.

Tokyo, Jun. 1, 2016



Hiroshi MARUSAWA

General Manager
Global Quality Assurance and
Regulatory Affairs
PENTAX Lifecare Division
HOYA Corporation

Authorized Representative in the European Union :
PENTAX Europe GmbH, Julius Vosseler Straße 104, 22527 Hamburg, Germany

PENTAX Life Care Division

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class IIa&IIb / RoHS

Model Name	MDD Class	Rule	Initial date of declaration of conformity	Serial/Lot Number	Remarks
DC-D2618	IIb	9	2016.6.1	B605443-	
DL-D2618	IIb	9	2016.6.1	B501390-	
DL-D2622	IIb	9	2016.6.1	—	
DN-D2718A	IIb	9	2016.6.1	B602186-	
DN-D2718B	IIb	9	2016.6.1	B502150-	
DN-D2722A	IIb	9	2016.6.1	B601655-	
DN-D2722B	IIb	9	2016.6.1	B601380-	
DO-D2618	IIb	9	2016.6.1	B501080-	
DO-D2622	IIb	9	2016.6.1	B501130-	
DP-D2518	IIb	9	2016.6.1	B604337-	
DP-D2622	IIb	9	2016.6.1	B604284-	
EB-1170K	IIa	5	2016.6.1	H120632-	
EB-1570K	IIa	5	2016.6.1	H122438-	
EB-1572K	IIa	5	2016.6.1	G120015-	
EB-1575K	IIa	5	2016.6.1	H121085-	
EB15-J10	IIa	5	2016.6.1	A120008-	
EB-1970K	IIa	5	2016.6.1	H121697-	
EB-1970TK	IIa	5	2016.6.1	H120415-	
EB-1972K	IIa	5	2016.6.1	G120011-	
EB-1975K	IIa	5	2016.6.1	H120735-	
EB-1990I	IIa	5	2016.6.1	H110146-	
EB19-J10	IIa	5	2016.6.1	A120008-	
EC-2990FI	IIa	5	2016.6.1	H110034-	
EC-2990LI	IIa	5	2016.6.1	H110198-	
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EC-3490FK	IIa	5	2016.6.1	H120304-	
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EC-3490LK	IIa	5	2016.6.1	H120245-	
EC-3490MI	IIa	5	2016.6.1	—	
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EC34-I10L	IIa	5	2016.6.1	A110709-	
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EC-3890FI2	IIa	5	2016.6.1	H112559-	
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EC-3890TLK	IIa	5	2016.6.1	H120108-	
EC38-I10F	IIa	5	2016.6.1	A110999-	
EC38-I10F2	IIa	5	2016.6.1	A110794-	
EC38-I10L	IIa	5	2016.6.1	A111539-	
EC38-I10M	IIa	5	2016.6.1	A110444-	
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EC38-I10NL	IIa	5	2016.6.1	A110036-	
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ECY-1575K	IIa	5	2016.6.1	H120438-	
ED-3490TK	IIa	5	2016.6.1	H121416-	
ED34-I10T	IIa	5	2016.6.1	A110621-	
EE-1580K	IIa	5	2016.6.1	H120127-	
EG-1690K	IIa	5	2016.6.1	—	
EG16-K10	IIa	5	2016.6.1	A120318-	
EG-1870K	IIa	5	2016.6.1	—	
EG-2490K	IIa	5	2016.6.1	H120374-	
EG-2790I	IIa	5	2016.6.1	—	
EG-2790K	IIa	5	2016.6.1	H121177-	
EG27-I10	IIa	5	2016.6.1	A110899-	



List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class II a& II b / RoHS

Model Name	MDD Class	Rule	Initial date of declaration of conformity	Serial/Lot Number	Remarks
EG-290Kp	IIa	5	2016.6.1	H127399-	
EG-2990i	IIa	5	2016.6.1	H118721-	
EG-2990K	IIa	5	2016.6.1	H122541-	
EG-2990Zi	IIa	5	2016.6.1	H110202-	
EG29-i10	IIa	5	2016.6.1	A113584-	
EG-3490K	IIa	5	2016.6.1	H120712-	
EG-3890TK	IIa	5	2016.6.1	H120264-	
EPK-1000	IIa	2	2016.6.1	H016084-	
EPK-100p	IIa	2	2016.6.1	F013808-	
EPK-3000	IIa	2	2016.6.1	A020033-	
EPK-i5000	IIa	2	2016.6.1	E013560-	
EPK-i7000	IIa	2	2016.6.1	C010936-	
EPK-i7000(A)	IIa	2	2016.6.1	C010490-	
EPK-i7010	IIa	2	2016.6.1	A010107-	
EPK-p(C)	IIa	2	2016.6.1	B011594-	
ES-3870K	IIa	5	2016.6.1	H120214-	
FB-10V	IIa	5	2016.6.1	H110891-	
FB-15BS	IIa	5	2016.6.1	-	
FB-15RBS	IIa	5	2016.6.1	H111601-	
FB-15V	IIa	5	2016.6.1	H113137-	
FB-18BS	IIa	5	2016.6.1	-	
FB-18RBS	IIa	5	2016.6.1	H110788-	
FB-18V	IIa	5	2016.6.1	H112369-	
FB-19TV	IIa	5	2016.6.1	H110737-	
FB-8V	IIa	5	2016.6.1	H110744-	
FC-38FV	IIa	5	2016.6.1	H110906-	
FC-38LV	IIa	5	2016.6.1	H111645-	
FCN-15X	IIa	5	2016.6.1	-	
FCP-9P	IIa	5	2016.6.1	H110335-	
FCY-15RBS	IIa	5	2016.6.1	H111082-	
FD-34V2	IIa	5	2016.6.1	H110286-	
FG-16V	IIa	5	2016.6.1	H110433-	
FG-24V	IIa	5	2016.6.1	H112083-	
FG-29V	IIa	5	2016.6.1	H117736-	
FHY-10RBS	IIa	5	2016.6.1	H110282-	
FHY-15RBS	IIa	5	2016.6.1	H110202-	
FI-10BS	IIa	5	2016.6.1	-	
FI-10RBS	IIa	5	2016.6.1	H111270-	
FI-13BS	IIa	5	2016.6.1	-	
FI-13RBS	IIa	5	2016.6.1	H110696-	
FI-16BS	IIa	5	2016.6.1	-	
FI-16RBS	IIa	5	2016.6.1	H111530-	
FI-7BS	IIa	5	2016.6.1	-	
FI-7RBS	IIa	5	2016.6.1	H110318-	
FI-9BS	IIa	5	2016.6.1	-	
FI-9RBS	IIa	5	2016.6.1	H110638-	
FNL-10RBS	IIa	5	2016.6.1	H115649-	
FNL-10RP3	IIa	5	2016.6.1	H141695-	
FNL-15RP3	IIa	5	2016.6.1	H112263-	
FNL-7RP3	IIa	5	2016.6.1	H115067-	
FS-34V	IIa	5	2016.6.1	H111651-	
FUR-9RBS	IIa	5	2016.6.1	H110218-	
HDB2418	IIb	9	2016.6.1	-	
HDB2418W	IIb	9	2016.6.1	J604202-	
HDB2422	IIb	9	2016.6.1	-	
HDB2422W	IIb	9	2016.6.1	J601511-	
H-52518	IIb	9	2016.6.1	D311610-	
H-52522	IIb	9	2016.6.1	D513053-	
HS-D2618	IIb	9	2016.6.1	to be fixed later	
HS-D2622	IIb	9	2016.6.1	to be fixed later	
LH-150PC	IIa	2	2016.6.1	B043790-	
OF-B205	IIa	5	2016.6.1	0011026-	
OS-H3	IIa	2	2016.6.1	0021046-	
OS-H4	IIa	2	2016.6.1	0051046-	
OS-H5	IIa	2	2016.6.1	0081026-	
VNL-1070STK	IIa	5	2016.6.1	H120233-	
VNL-1190STK	IIa	5	2016.6.1	H120300-	
VNL11-J10	IIa	5	2016.6.1	A120014-	
VNL-1570STK	IIa	5	2016.6.1	H120446-	
VNL-1590STi	IIa	5	2016.6.1	H110250-	
VNL15-J10	IIa	5	2016.6.1	A120003-	
VNL8-J10	IIa	5	2016.6.1	A120012-	
VSB-2990i	IIa	5	2016.6.1	H110095-	



認

証

この書面における HOYA 株式会社 PENTAX ライフケア事業
部品質保証部部長丸澤宏の代理人吉川真祐子は、本職の面前
において被代理人がその署名を自認する旨陳述した。

よって、これを認証する。

平成28年

6 月 17

日、本公証人役場において

東京都豊島区東池袋3丁目1番1号
東京法務局所属

公 証 人
Notary

佐藤 進

SUSUMU HIBUCHI

証

明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、
真実のものであることを証明する。

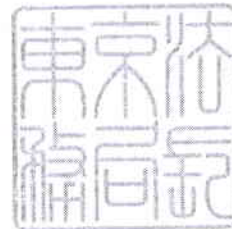
平成28年

6 月 17

日

東京法務局長

佐藤主税



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN

This public document

2. has been signed by

SUSUMU HIBUCHI

3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau

4. bears the seal/stamp of SUSUMU HIBUCHI ,Notary

Certified

5. at Tokyo

6.

17 JUN 2016

7. by the Ministry of Foreign Affairs

8. 16-No 006830

9. Seal/stamp:

10. Signature



A. Ogawa

Ayako OGAWA

For the Minister for Foreign Affairs



品質保証部



Registered No. 223

NOTARIAL CERTIFICATE

This is to certify that MAYUKO YOSHIKAWA, an agent of HIROSHI MARUSAWA General Manager, Global Quality Assurance and Regulatory Affairs of HOYA Corporation PENTAX Lifecare Division, has stated in my presence that said HIROSHI MARUSAWA acknowledged to have signed the attached document.

Dated this 17 day of JUN. 2016

Susumu Iibuchi

SUSUMU IIBUCHI





(Translation)

C E R T I F I C A T E

This is to certify that the signature affixed above
has been provided by Notary, duly authorized by
the Tokyo Legal Affairs Bureau and that the Official
Seal appearing on the same is genuine.

Date

17 JUN 2016

Director of the Tokyo Legal Affairs Bureau

佐藤 主税

(Chikara SATO)

Official
Seal



**TAX
BICAL**

«ХОЯ КОРПОРЕЙШН»
6-10-1 Ниси-Синдзюку, Синдзюку-ку,
Токио, 160-0023, Япония

**[ДЕКЛАРАЦИЯ СООТВЕТСТВИЯ ЕС
ER-QL-193]**

TAKS

15 июня 2016 года

месту требования

ПОДТВЕРЖДЕНИЕ

1. «ХОЯ Корпорейшн», (6-10-1 Ниси-Синдзюку, Синдзюку-ку, Токио, 160-0023, Япония),
утверждаем, что прилагаемый документ, указанный выше, является оригиналом
документа.

Подпись/

Ароси Марусава

Генеральный директор

Дел глобального обеспечения качества и нормативно-правового регулирования

Подразделение ПЕНТАКС Лайф Кеар



**TAX
ICAL****ДЕКЛАРАЦИЯ СООТВЕТСТВИЯ ЕС**

ХОЯ Корпорейшн
6-10-1 Ниси-Синдзюку, Синдзюку-ку,
Токио, 160-0023, Япония

Настоящей ответственностью заявляем, что продукция под торговой маркой «ПЕНТАКС» (PENTAX)
«ПЕНТАКС Медикал» (PENTAX Medical):

Наименование продукции: Эндоскопы, видеопроцессоры и принадлежности к ним

Номер модели: См. приложение

Отвечает:

Процедуре оценки соответствия, указанной в Приложении II в соответствии с положениями Директивы 93/42/ЕЕС «О медицинских изделиях». Классификация и правила, применяемые к каждой модели, описаны в приложении.

Настоящая декларация основывается на системе качества ЕС, утвержденной TÜV SÜD Product Service GmbH (№ 0123), Ридлерштрассе 65, 80339 Мюнхен, Германия

В соответствии с положениями Директивы по ограничению вредных веществ 2011/65/EU.

Токио, 1 июня 2016 г.

[Подпись]

Хироки МАРУСАВА
Генеральный директор
Отдел глобального обеспечения качества и
нормативно-правового регулирования
Подразделение ПЕНТАКС Лайф Кеар
«ХОЯ Корпорейшн»

полномоченный представитель в ЕС:

PENTAX Europe GmbH, Юлиус Фосселер Штрассе 104, 22527 г.Гамбург, Германия

Подразделение PENTAX Life Care

Номер формы: ET-TR-010-Form51

Версия формы: R03



Исход изделий с маркировкой CE

Категория: Эндоскопы, видеопроцессоры и принадлежности к ним

Изделия класса IIa и IIb в соответствии с Директивой о медицинских изделиях/Директивой об ограничении опасных веществ

Номер модели	Класс по MDD	Правило	Первоначальная дата выдачи Декларации о соответствии	Номер серии/партии	Примечания
DC-D2618	IIb	9	01.06.2016	B605443-	
DL-D2618	IIb	9	01.06.2016	B501390-	
DL-D2622	IIb	9	01.06.2016	-	
DN-D2718A	IIb	9	01.06.2016	B602186-	
DN-D2718B	IIb	9	01.06.2016	B502150-	
DN-D2722A	IIb	9	01.06.2016	B601655-	
DN-D2722B	IIb	9	01.06.2016	B601380-	
DO-D2618	IIb	9	01.06.2016	B501080-	
DO-D2622	IIb	9	01.06.2016	B501130-	
DP-D2518	IIb	9	01.06.2016	B604337-	
DP-D2622	IIb	9	01.06.2016	B604284-	
EB-1170K	IIa	5	01.06.2016	H120632-	
EB-1570K	IIa	5	01.06.2016	H122438-	
EB-1572K	IIa	5	01.06.2016	G120015-	
EB-1575K	IIa	5	01.06.2016	H121085-	
EB15-J10	IIa	5	01.06.2016	A120008-	
EB-1970K	IIa	5	01.06.2016	H121697-	
EB-1970TK	IIa	5	01.06.2016	H120415-	
EB-1972K	IIa	5	01.06.2016	G120011-	
EB-1975K	IIa	5	01.06.2016	H120735-	
EB-1990i	IIa	5	01.06.2016	H110146-	
EB19-J10	IIa	5	01.06.2016	A120908-	
EC-2990Fi	IIa	5	01.06.2016	H110034-	
EC-2990Li	IIa	5	01.06.2016	H110198-	
EC-2990Mi	IIa	5	01.06.2016	H110021-	
EC-3490Fi	IIa	5	01.06.2016	-	
EC-3490FK	IIa	5	01.06.2016	H120304-	
EC-3490Li	IIa	5	01.06.2016	-	
EC-3490LK	IIa	5	01.06.2016	H120245-	
EC-3490Mi	IIa	5	01.06.2016	-	
EC-3490MK	IIa	5	01.06.2016	H120052-	
EC-3490TFi	IIa	5	01.06.2016	H110246-	
EC-3490TLi	IIa	5	01.06.2016	H110591-	
EC-3490TMi	IIa	5	01.06.2016	H110063-	
EC34-i10F	IIa	5	01.06.2016	A110387-	
EC34-i10L	IIa	5	01.06.2016	A110709-	
EC34-i10M	IIa	5	01.06.2016	A110143-	
EC-380FK2p	IIa	5	01.06.2016	H122904-	
EC-380FKp	IIa	5	01.06.2016	H121099-	
EC-380LKp	IIa	5	01.06.2016	H122680-	
EC-380MK2p	IIa	5	01.06.2016	H120272-	
EC-3890Fi	IIa	5	01.06.2016	H111703-	
EC-3890Fi2	IIa	5	01.06.2016	H112559-	
EC-3890FK	IIa	5	01.06.2016	H120749-	
EC-3890FK2	IIa	5	01.06.2016	H121049-	
EC-3890FZi	IIa	5	01.06.2016	H110084-	
EC-3890Li	IIa	5	01.06.2016	H116211-	
EC-3890LK	IIa	5	01.06.2016	H120935-	
EC-3890Li2i	IIa	5	01.06.2016	H110061-	
EC-3890Mi	IIa	5	01.06.2016	-	
EC-3890Mi2	IIa	5	01.06.2016	-	
EC-3890MK	IIa	5	01.06.2016	H120120-	
EC-3890MK2	IIa	5	01.06.2016	H120086-	
EC-3890MZi	IIa	5	01.06.2016	H110044-	
EC-3890TFK	IIa	5	01.06.2016	H120051-	
EC-3890TLK	IIa	5	01.06.2016	H120108-	
EC38-i10F	IIa	5	01.06.2016	A110999-	
EC38-i10F2	IIa	5	01.06.2016	A110794-	
EC38-i10L	IIa	5	01.06.2016	A111539-	
EC38-i10M	IIa	5	01.06.2016	A110444-	
EC38-i10M2	IIa	5	01.06.2016	A110111-	
EC38-i10NF	IIa	5	01.06.2016	A110045-	
EC38-i10NL	IIa	5	01.06.2016	A110036-	
ECY-1570K	IIa	5	01.06.2016	H120415-	
ECY-1575K	IIa	5	01.06.2016	H120438-	
ED-3490TK	IIa	5	01.06.2016	H121416-	
ED34-i10T	IIa	5	01.06.2016	A110621-	
EE-1580K	IIa	5	01.06.2016	H120127-	
EG-1690K	IIa	5	01.06.2016	-	
EG16-K10	IIa	5	01.06.2016	A120318-	
EG-1870K	IIa	5	01.06.2016	-	
EG-2490K	IIa	5	01.06.2016	H120374-	
EG-2790i	IIa	5	01.06.2016	-	
EG-2790K	IIa	5	01.06.2016	H121177-	
EG27-i10	IIa	5	01.06.2016	A110899-	

Список изделий с маркировкой CE

Категория: Эндоскопы, видеопроцессоры и принадлежности к ним

Изделия класса IIa и IIb в соответствии с Директивой о медицинских изделиях/Директивой об ограничении опасных веществ

Номер модели	Класс по MDD	Правило	Первоначальная дата выдачи Декларации о соответствии	Номер серии/партии	Примечания
IG-290Kp	IIa	5	01.06.2016	H127399-	
IG-2990i	IIa	5	01.06.2016	H118721-	
IG-2990K	IIa	5	01.06.2016	H122541-	
IG-2990Zi	IIa	5	01.06.2016	H110262-	
IG29-110	IIa	5	01.06.2016	A113584-	
IG-3490K	IIa	5	01.06.2016	H120712-	
IG-3890TK	IIa	5	01.06.2016	H120264-	
EPK-1000	IIa	2	01.06.2016	H016084-	
EPK-100p	IIa	2	01.06.2016	F013808-	
EPK-3000	IIa	2	01.06.2016	A020033-	
EPK-i5000	IIa	2	01.06.2016	E013560-	
EPK-i7000	IIa	2	01.06.2016	C010936-	
EPK-i7000(A)	IIa	2	01.06.2016	C010490-	
EPK-i7010	IIa	2	01.06.2016	A010107-	
EPK-p(C)	IIa	2	01.06.2016	B011594-	
ES-3870K	IIa	5	01.06.2016	H120214-	
FB-10V	IIa	5	01.06.2016	H110891-	
FB-15BS	IIa	5	01.06.2016	-	
FB-15RBS	IIa	5	01.06.2016	H111601-	
FB-15V	IIa	5	01.06.2016	H113137-	
FB-18BS	IIa	5	01.06.2016	-	
FB-18RBS	IIa	5	01.06.2016	H110788-	
FB-18V	IIa	5	01.06.2016	H112369-	
FB-19TV	IIa	5	01.06.2016	H110737-	
FB-8V	IIa	5	01.06.2016	H110744-	
FC-38FV	IIa	5	01.06.2016	H110906-	
FC-38LV	IIa	5	01.06.2016	H111645-	
FCN-15X	IIa	5	01.06.2016	-	
FCP-9P	IIa	5	01.06.2016	H110335-	
FCY-15RBS	IIa	5	01.06.2016	H111082-	
FD-34V2	IIa	5	01.06.2016	H110286-	
FG-16V	IIa	5	01.06.2016	H110433-	
FG-24V	IIa	5	01.06.2016	H112083-	
FG-29V	IIa	5	01.06.2016	H117736-	
FHY-10RBS	IIa	5	01.06.2016	H110282-	
FHY-15RBS	IIa	5	01.06.2016	H110202-	
FI-10BS	IIa	5	01.06.2016	-	
FI-10RBS	IIa	5	01.06.2016	H111270-	
FI-13BS	IIa	5	01.06.2016	-	
FI-13RBS	IIa	5	01.06.2016	H110696-	
FI-16BS	IIa	5	01.06.2016	-	
FI-16RBS	IIa	5	01.06.2016	H111530-	
FI-7BS	IIa	5	01.06.2016	-	
FI-7RBS	IIa	5	01.06.2016	H110318-	
FI-9BS	IIa	5	01.06.2016	-	
FI-9RBS	IIa	5	01.06.2016	H110638-	
FNL-10RBS	IIa	5	01.06.2016	H115649-	
FNL-10RP3	IIa	5	01.06.2016	H141695-	
FNL-15RP3	IIa	5	01.06.2016	H112263-	
FNL-7RP3	IIa	5	01.06.2016	H115067-	
FS-34V	IIa	5	01.06.2016	H111651-	
FUR-9RBS	IIa	5	01.06.2016	H110218-	
HDB2418	IIb	9	01.06.2016	-	
HDB2418W	IIb	9	01.06.2016	J604202-	
HDB2422	IIb	9	01.06.2016	-	
HDB2422W	IIb	9	01.06.2016	J601511-	
H-S2518	IIb	9	01.06.2016	D311610-	
H-S2522	IIb	9	01.06.2016	D513053-	
HS-D2618	IIb	9	01.06.2016	Будет определен позднее	
HS-D2622	IIb	9	01.06.2016	Будет определен позднее	
LIT-150PC	IIa	2	01.06.2016	B043790-	
OF-B205	IIa	5	01.06.2016	0011026-	
OS-H3	IIa	2	01.06.2016	0021046-	
OS-H4	IIa	2	01.06.2016	0051046-	
OS-H5	IIa	2	01.06.2016	0081026-	
VNL-1070STK	IIa	5	01.06.2016	H120233-	
VNL-1190STK	IIa	5	01.06.2016	H120300-	
VNL11-J10	IIa	5	01.06.2016	A120014-	
VNL-1570STK	IIa	5	01.06.2016	H120446-	
VNL-1590STi	IIa	5	01.06.2016	H110250-	
VNL15-J10	IIa	5	01.06.2016	A120003-	
VNL8-J10	IIa	5	01.06.2016	A120012-	
VSB-2990i	IIa	5	01.06.2016	H110095-	

ТЕКСТ НА ЯПОНСКОМ ЯЗЫКЕ
ДУБЛИРУЕТСЯ НА АНГЛИЙСКОМ НА
СЛЕДУЮЩЕЙ СТРАНИЦЕ

АПОСТИЛЬ

(Гаагская конвенция от 5 октября 1961 г.)

1. Страна: **ЯПОНИЯ**

Данный официальный документ

2. был подписан **СУСУМИ ИИБУЧИ**

3. выступающим в качестве Нотариуса Токийского бюро по юридическим вопросам

4. скреплен печатью/штампом **СУСУМИ ИИБУЧИ, нотариуса**

Удостоверено

5. в г. Токио

6. 17 июня 2016 года

7. Министерством иностранных дел

8. 16- № 006830

9. Печать/штамп:

10. Подпись

[Подпись]

Айяко ОГАВА

От имени Министра иностранных дел

Печать: МИНИСТЕРСТВО ИНОСТРАННЫХ ДЕЛ. ЯПОНИЯ.

Печати на японском языке.



НОТАРИАЛЬНОЕ СВИДЕТЕЛЬСТВО

Настоящим свидетельствуется, что МАЮКО ЙОШИКАВА, представитель ХИРОСИ МАРУСАВА, генерального директора, Отдела глобального обеспечения качества и нормативно-правового регулирования Подразделения ПЕНТАКС Лайф Кеар компании «ХОЯ КОРПОРЕЙШН», заявил в моем присутствии о том, что упомянутый ХИРОСИ МАРУСАВА подтвердил, что он подписал прилагаемый документ.

Датировано сего 17 числа июня месяца 2016 года.

[Подпись]

СУСУМИ ИИБУЧИ

Печать: Токийское бюро по юридическим вопросам. НОТАРИУС.
1-1, Хигаши-Икебукуро 3-тёме
Тошима-ку, г. Токио, Япония.

Печать на японском языке.



(Перевод)

СВИДЕТЕЛЬСТВО

Настоящим свидетельствуется, что подпись, прилагаемая выше, была поставлена нотариусом, надлежащим образом на это уполномоченным Токийским бюро по юридическим вопросам, и что официальная печать на документе является подлинной.

Дата: 17 июня 2016 г.

Директор Токийского бюро по юридическим вопросам.

[Подпись]
(Чикара САТО)

Официальная печать:

