Anexa 3

Specificare tehnică 3: Sistem de diagnosticare ultrasonor

Model: Logiq Fortis + VscanAir; Producator: GE Ultrasound Korea, GE Medical Systems SCS +GE Vigmed Ultrasound AS, GE Healthcare Austria GmbH; Tara: Korea si Franta + Norvegia, Austria

CARACTERISITICI TEHNICE DEPLIN SOLICITATE	Specificatia Tehnica porpusa si confirmata
A) UNITATEA ECOGRAFICA CU URMATOARELE CARACTERISTICI MINIME:	
Echipament stationar multidisciplinar de ultrasonografie de inalta performanta conceput pentru examinari abdominale, ale sistemului vascular, obstetrica si ginecologie, neonatale, pediatrice, urologice, transcraniale, cardiace si pentru parti moi, etc.	**Conform LOGIQ Fortis Datasheet, pag. 2** – Applications: Abdominal, Obstetrical, Gynecological, Breast, Small Parts, Peripheral Vascular, Transcranial (adult and neonatal), Pediatric and Neonatal, Musculoskeletal (general and superficial), Urological, Cardiac (adult and pediatric), Interventional, Pleural
CARACTERISTICI CONSTRUCTIVE, STRUCTURALE SI DIMENSIONALE	
Sistem stationar cu urmatoarele caracateristici:	
- patru roti pentru stabilitatea in deplasarea si pozitionarea cu posibilitate de blocare a cel putin 2 roti	**Conform LOGIQ Fortis – Basic User Manual ENG, pag. 3-6 /104** – Console Graphics: 19. Wheel Brake (with each caster)
- rotile sa poata fi blocate pentru deplasarea in linie dreapta	
Tehnologie moderna la gabarit redus:	
Sistemul sa dispuna de dimensiuni reduse pentru o mobilitate si usurinta in manipulare crescuta maxim 1770x53x87 cm (inaltime x latime x adancime)	**Conform LOGIQ Fortis Datasheet, pag. 2** – Applications: Depth: 885 mm, 34.8", Height: 1250 – 1800 mm, 49 – 71", Width: 530 mm, 20.9" (Caster), 565 mm, 22.2" (Monitor)
Consum maxim: 900 VA - inclusiv cu periferice	**Conform LOGIQ Fortis Datasheet, pag. 2** – Electrical Power: Power consumption maximum of 0.9 kVA with peripherals
Consola de comanda a ecografului are posibilitatea de a se deplasa atat in plan vertical cat si in plan orizontal	**Conform LOGIQ Fortis Datasheet, pag. 2** – Electrical Power: Operating keyboard adjustable in height and rotation
Consola prezinta posibilitatea de a se deplasa concomitent cu monitorul fara a-i afecta acestuia gradele de libertate independente	**Conform LOGIQ Fortis Spec Sheet, pag. 1** – Monitor: Display translation (independent of console)
Consola este prevazuta cu un sistem de asigurare al cablurilor	**Conform LOGIQ Fortis Datasheet, pag. 2** – Console design: Integrated cable management
Consola dispune de porturi integrate pentru instalarea perifericelor situate in partea frontala a echipamentului	**Conform LOGIQ Fortis Datasheet, pag. 3-6** – LOGIQ Fortis – Basic User Manual: 8. DVD Drive, Blind cover, B/W printer, V-Nav controller, ECG connector

Anexa 3

DESCRIEREA CONSOLEI:	
Monitor cu tehnologie de tip OLED sau superior tehnologiei LED	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: 23.8" Widescreen high-resolution HDU Display
Diagoanala monoitorului minim 23.5 inch	
Monitorul este prevazut cu tehnologie anti reflex pentru a inlatura reflexia luminii pe ecranul de diagnostic	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: Anti-glare
Rezolutia monitorului: 1920x1080	**Conform LOGIQ Fortis Datasheet, pag.** 2 – Display monitor: Resolution: 1920 x 1080
Rata de contrast a monitorului mai mare de 23.000:1	**Conform LOGIQ Fortis Spec Sheet, pag. 1** – Monitor: Contrast Ratio: >20,000:1
Unghi orizontal/vertical de vizualizare: minim +/- 85º	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: Viewing angle 89/89/89/89°
Posibilitate de ajustare a contrastului si luminozitatii	**Conform LOGIQ Fortis – Basic User Manual, pag. 12-2** – HDU Display: Brightness & contrast adjustment
Monitorul este plasat pe un brat articulat care sa permita deplasarea in toate planurile:	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: Display translation (independent of console)
- rotatii minime: >175°	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: 90° swivel (both directions)
- deplasarea pe orizontala: > 345 mm in ambele directii	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: 350 mm (13.7") horizontal (both directions)
- deplasare pe verticala: > 115 mm	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: 120 mm (4.7") vertical
Monitorul dispune de mecanism de blocare pentru transportul in siguranta	**Conform LOGIQ Fortis Datasheet, pag. 2** – Display monitor: Fold-down and lock mechanism for transportation
Ecograful dispune de cel putin 4 porturi active pentru sonde si un port pentru parcare	**Conform LOGIQ Fortis Datasheet, pag. 2** – Console design: 4 active probe ports, 1 inactive probe storage port
Consola este prevazuta cu filtre de particule. Acestea pot fi accesate si curatate usor, fara a fi nevoie de instrumente suplimentare sau de demontare	**Conform LOGIQ Fortis Datasheet, pag. 2** – Console design: Easily removable air filters
Sistemul prezinta boxe integrate pentru frecvente joase ce asigura o acustica fidela	**Conform LOGIQ Fortis Datasheet, pag. 2** – Console design: Integrated speaker
INTERFATA CU UTILIZATORUL	
Indeplineste urmatoarele caracteristici:	
Ecran de comanda tactil color de inalta rezolutie	**Conform LOGIQ Fortis Datasheet, pag. 2** – Touch screen: 12.1" High-resolution, color, touch display screen
Diagonala ecranului tactil de peste 12 inch	**Conform LOGIQ Fortis Datasheet, pag. 2** – Touch screen: 12.1" High-resolution, color, touch display screen
Pentru optimizarea fluxului de lucru, interfața software oferă posibilitatea de a editata profiluri individuale de utilizator pentru personalizarea preferințelor	**Conform LOGIQ Fortis Datasheet, pag. 2** – Touch screen: User-configurable layout

Ecograful este prevazut cu tastatura alfanumerica. Aceasta detine taste iluminate	**Conform LOGIQ Fortis Datasheet, pag. 2** – Operator keyboard: Operating keyboard, adjustable in height and rotation, Interactive back-lighting **Conform LOGIQ Fortis – Basic User Manual, pag. 3-54 –** Physical A/N keyboard: Physical A/N keyboard is under the control panel.
Prezinta posibilitatea de a ajusta nivelul de iluminare a tastaturii pentru intuneric si semi-intuneric	**Conform LOGIQ Fortis Datasheet, pag. 2** – Operator keyboard: Operating keyboard, adjustable in height and rotation, Interactive back-lighting
Ecograful dispune de taste de control configurabile pentru activarea functiilor a cel putin 4 dispozitive periferice externe (imprimante, comunicare DICOM, memorie de lunga durata)	**Conform LOGIQ Fortis Datasheet, pag. 2** – Operator keyboard: Integrated recording keys for remote control of up to 4 peripheral or DICOM® devices
Posibilitate de ugrade cu modul ce permite comunicare DICOM	**Conform LOGIQ Fortis Datasheet, pag. 4** – Options: DICOM
Dispune de suport integrat pentru tubul de gel cu sistem de incalzire a gelului	**Conform LOGIQ Fortis Datasheet, pag. 2** – Operator keyboard: Integrated gel warmer
Echipamentul dispune de platforma ce ofera utilizatorului accesarea rapida la suportul tehnic autorizat de producator	**Conform LOGIQ Fortis Datasheet, pag. 3** – System standard features: InSite™ capability
MODURI DE OPERARE:	
Moduri de functionare fundamentale:	
- mod de tip M	**Conform LOGIQ Fortis Datasheet, pag. 3** – Operating modes: M-Mode
- mod de tip 2D	**Conform LOGIQ Fortis Datasheet, pag.** 3 – Operating modes: B-Mode
- mod Doppler (Color, Power, Spectral)	**Conform LOGIQ Fortis Datasheet, pag. 3** – Operating modes: Color Flow Mode (CFM), Power Doppler Imaging (PDI), PW Doppler
Moduri de functionare derivate si/sau combinate din cele fundamentale:	
- mod tip M Anatomic cu posibilitatea plasarii cursorului in orice plan	**Conform LOGIQ Fortis Datasheet, pag.** 3 – Operating modes: Anatomical M-Mode: M-Mode cursor adjustable at any plane
- mod tip M Anatomic cu posibilitatea de plasare a cursorului independent de planul axial ce permite inregistrarea de informatii suplimentare, fara limitare de pozitionare liniara	**Conform LOGIQ Fortis Datasheet, pag. 10** – TVI (Option): Curved anatomical M-Mode: free (curved) drawing of M-Mode generated from the cursor independent of the axial plane
- dispune de posibilitate de upgradare cu Mod Doppler Continuu	**Conform LOGIQ Fortis Datasheet, pag. 4** – Options: CW

Are capacitatea de a functiona cu 3 moduri de lucru active in acelasi timp (triplex)	**Conform LOGIQ Fortis Datasheet, pag. 4** – Simultaneous capability: Real-time Triplex Mode
Dispune de posibilitate de upgradare, in vederea analizei corecte a evolutiei diagnosticului, cu mod ce permite compararea examinarilor precedente ale unui pacient, cu imagini ale examinarii curente. Astfel sincronizeaza automat toti parametrii imaginii examenului curent in scopul folosirii acelorasi conditii de examinare	**Conform LOGIQ Fortis Datasheet, pag. 9 – Compare assistant (Option):** Allows side-by-side comparison of previous ultrasound and other modality exams during live scanning **Conform LOGIQ Fortis – Basic User Manual, pag. 13-379 – Compare Assistant:** In B-Mode the following parameters can be transferred from the Compared Image to the Active B-Mode Image, In Color Flow/PDI Mode the following parameters can be transferred from the Compared Image to the Active Color Flow/ PDI Mode image
CARACTERISTICI ALE SONDELOR:	
Sondele disponibile prezinta in componenta materiale piezoelectrice de ultima generatie ce permit emisia pe o latime de banda mai mare, la acelasi nivel de elevatie, fata de cristalele tip PZT (tehnologie de tip cristal unic)	**Conform LOGIQ Fortis Datasheet, pag. 14** – Probes: C1-6-D, XDclear™ convex probe
Echipamentul dispune de sonde matriciale cu peste 950 cristale pentru controlul focalizarii in elevatie a fasciculului de ultrasunete si obtinerea unor imagini cu rezolutie de o buna calitate	**Conform LOGIQ Fortis Spec Sheet, pag. 19** – Probes (All Optional): ML6-15-D, matrix array linear probe: Number of elements: 1008
Adancimea minima de scanare este <0.2 cm	**Conform LOGIQ Fortis Datasheet, pag. 7** – Scanning parameters: Minimum depth of field: 0 – 2 cm (zoom) (probe dependent)
Adancimea maxima de scanare este >95 cm	**Conform LOGIQ Fortis Datasheet, pag. 7** – Scanning parameters: Maximum depth of field: 0 – 100 cm (probe dependent)
TIPURI DE TRADUCTORI COMPATIBILI CU ECOGRAFUL	
Sonde in care sunt inglobate din punct de vedere arhitectural, tehnologiile: cristal pur, tehnologie de amplificare a semnalului emis in vederea cresterii puterii de emisie a fasciculului de ultrasunete si receptionarea amplificata a semmnalelor utile slabe si tehnologie integrata de racire activa a cristalelor pentru scanarea pe perioade indelungate	**Conform LOGIQ Fortis Datasheet, pag. 14** – Probes: C1-6-D, XDclear™ convex probe
Traductori de tip:	
- convex (convex, micro-convex, endocavitar, endocavitar 4D, biplan, volumetric) acopera in intregime domeniul 1 - 11.8 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 1, 3 –** C1-6-D: Bandwidth: 1 – 6 MHz, C3-10-D: Bandwidth: 2 – 11 MHz, IC5-9-D: Bandwidth: 3 – 10 MHz, RIC5-9-D: Bandwidth: 3 – 10 MHz, BE9CS-D: Bandwidth: 3 – 12 MHz

- micro-convex pentru pediatrie ce prezinta campul de vizualizare de peste 90°	**Conform LOGIQ Fortis Probe Guide, pag. 1 –** C3-10-D: FOV: 95º
- micro-convex endocavitar ce acopera in intregime domeniul de frecventa 3 - 10 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 1 –** IC5-9-D: Bandwidth: 3 – 10 MHz
- micro-convex endocavitar ce prezinta campul de vizualizare de peste 175°	**Conform LOGIQ Fortis Probe Guide, pag. 1 –** IC5-9-D: FOV: 180º
- micro-convex endocavitar volumetric ce prezinta campul de vizualizare de peste 175°	**Conform LOGIQ Fortis Probe Guide, pag. 3 –** RIC5-9-D: FOV: 180º
- liniar (liniar, matriceal, tip "Hockeystick") acopera in intregime domeniul 2 - 19.5 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 2 –** L2-9-D: Bandwidth: 2 – 10 MHz, L3-12-D: Bandwidth: 2 – 11 MHz, L6-24-D: Bandwidth: 6 – 20 MHz, L8-18i-D: Bandwidth: 4 – 15 MHz, ML6-15-D: Bandwidth: 4 – 16 MHz
- tip "Hockey Stick" acopera in intregime domeniul de frecventa 4.2 - 15 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 2 –** L8-18i-D: Bandwidth: 4 – 15 MHz
- liniar intraoperatori acopera in intregime domeniul de frecventa 2 - 15 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 2 –** L8-18i-D: Bandwidth: 4 – 15 MHz
- liniar ce prezinta tehnologie de peste 980 de cristale	**Conform LOGIQ Fortis Spec Sheet, pag. 19 – Probes (All Optional):** ML6-15-D, matrix array linear probe: Number of elements: 1008
- sectorial arie fazata (transtoracic, transtoracic matriceal, transesofagian) acopera in intregime domeniul 1 - 7.8 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 3 –** M5Sc-D: Bandwidth: 1 – 5 MHz, 6S-D: Bandwidth: 2 – 8 MHz, 6Tc-RS: Bandwidth: 2 – 8 MHz
- transesofagian ce acopera in intregime domeniul de frecventa 2.2 - 8 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 3 –** 6Tc-RS: Bandwidth: 2 – 8 MHz
- de tip biplan cu ungiul de vizualizare de peste 130 de grade	**Conform LOGIQ Fortis Probe Guide, pag. 3 –** BE9CS-D: FOV: 133º
- de specialitate tip creion ce acopera in intregime domeniul 1 - 7 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 3 –** P2D: Bandwidth: 1 – 3 MHz, P6D: Bandwidth: 5 – 7 MHz
PROCESAREA IMAGINII:	
In functie de ecogenitatea structurii analizate si timp, echipamentul prezinta posibilitatea de modificare liniara a coeficientului de amplificare	**Conform LOGIQ Fortis Datasheet, pag. 10, 11** – Controls available while “live”: B/M/CrossXBeam-Mode: Gain, TGC, PW-Mode: Gain, Color Flow Mode: CFM gain
Focalizare dinamica continua in recepție	**Conform LOGIQ Fortis Datasheet, pag. 7** – Scanning parameters: Continuous dynamic

	receive focus/continuous dynamic receive Aperture
Gama dinamica ajustabila a sistemului este de peste 500 dB	**Conform LOGIQ Fortis Spec Sheet, pag. 7** – Scanning parameters: Adjustable dynamic range, inifinite upper level
Formator de unde de ultimă generație, cu minim 950.000.000 de canale efective	**Conform LOGIQ Fortis Spec Sheet, pag. 7** – Scanning parameters: cSound™ Imageformer: Infinite number of effective channels
Frame rate-ul sistemului este peste 9.000 cadre pe secunda	**Conform LOGIQ Fortis Spec Sheet, pag. 7** – Scanning parameters: Frame rate: 9,675 Hz maximum
Sistemul lucreaza cu frecvente cuprinse cel putin in intervalul 0.7 - 23.5 MHz	**Conform LOGIQ Fortis Spec Sheet, pag. 7** – Scanning parameters: System Frequency Range: 0.7-24 MHz
Tehnică adaptiva de analiza comparativă a tuturor pixelilor ce permite reducerea artefactelor si îmbunătățește calitatea imaginii, permițând o vizualizare mai precisă a detaliilor morfologice.	**Conform LOGIQ Fortis Datasheet, pag. 10** – SRI-HD and Advanced SRI: Speckle reduction imaging, Provides multiple levels of speckle reduction
Aceasta tehnica de imbunatatire a imaginii este compatibila atat cu traductorii liniari, cat si cu traductorii de tip convex si sectorial	**Conform LOGIQ Fortis Datasheet, pag. 10** – SRI-HD and Advanced SRI: Advanced SRI: two types selectable: Type 1 – Compatible with all linear, convex, and sector probes
Dispune de posibilitate de upgradare cu tehnică adaptiva de analiza comparativă a tuturor pixelilor ce permite reducerea artefactelor si îmbunătățește calitatea imaginii, permițând o vizualizare mai precisă a detaliilor morfologice, compatibilă cu aplicațiile de obstetrică-ginecologie.	**"Conform LOGIQ Fortis Datasheet, pag. 10** – SRI-HD and Advanced SRI: Speckle reduction imaging, Provides multiple levels of speckle reduction, Advanced SRI: two types selectable: Type 2 (Option) – Compatible with OB/GYN application
Prezinta posibilitatea largirii campului vizual la functionarea cu traductori liniari si sectoriali in scopul afisarii pe ecran a unor zone suplimentare de tesut	**Conform LOGIQ Fortis Datasheet, pag. 10** – Virtual convex: Available on all linear and sector probes
Metoda de investigare ce permite achiziționarea și vizualizarea in ansamblu a unor zone largi de scanare cu o lungime de peste 155 cm	**Conform LOGIQ Fortis Datasheet, pag. 8** – LOGIQView: Extended field of view Imaging, Up to 160 cm (63") scan length
Aceasta tehnologie permite atat selectarea automata a celei mai bune pozitii din ecran cat si detectarea automata a directiei de scanare cu posibilitate de rotire, zoom si efectuare de masuratori pe imaginea panoramica	**Conform LOGIQ Fortis Datasheet, pag. 8** – LOGIQView: Auto detection of scan direction, Pre-or post-process zoom, Rotation, Auto best fit on monitor, Measurements in B-Mode

Tehnologie de interpolare a cadrelor aflate sub unghiuri diferite de vizualizare pentru reducerea semnificativa a zgomotului de fond din imagine si este compatibila cu urmatoarele moduri de lucru/tehnici:	**Conform LOGIQ Fortis Datasheet, pag. 10** – CrossXBeam: Provides variable angle spatial compounding
- modul Color	**Conform LOGIQ Fortis Datasheet, pag. 10** – CrossXBeam: Compatible with: Color mode, PW, SRI-HD, Coded harmonic imaging, Virtual convex
- modul Doppler Pulsat	**Conform LOGIQ Fortis Datasheet, pag. 10 – CrossXBeam:** Compatible with: Color mode, PW, SRI-HD, Coded harmonic imaging, Virtual convex
- tehnica adaptiva pentru inlaturarea artefactelor	**Conform LOGIQ Fortis Datasheet, pag. 10 – CrossXBeam:** Compatible with: Color mode, PW, SRI-HD, Coded harmonic imaging, Virtual convex
- tehnica de largire a campului vizual	**Conform LOGIQ Fortis Datasheet, pag. 10 – CrossXBeam:** Compatible with: Color mode, PW, SRI-HD, Coded harmonic imaging, Virtual convex
Permite afisarea pe ecran in timp real atat pentru imaginea bidimensionala nativa, obtinuta prin emisia semnalelor acustice intr-un singur plan, cat si pentru imaginea rezultata prin sumarea ecourilor obtinute in urma emisiei semnalelor acustice in mai multe planuri	**Conform LOGIQ Fortis Datasheet, pag. 4 – Simultaneous capability:** B/CrossXBeam
STOCAREA IMAGINII:	
Capactatea de stocare (HDD) de minim 700 GB	**Conform LOGIQ Fortis Datasheet, pag. 6 – Image storage:** Storage devices: Hard drive image storage: ~730GB
Arhitectura de lucru privind salvarea datelor in formatul brut, ceea ce inseamna ca imaginile sunt captate inaintea lanțului de procesare, permite utilizatorilor să efectueze urmatoarele modificări chiar după terminarea examenului ca o re-scanare virtuala mai amănunțită:	**Conform LOGIQ Fortis Datasheet, pag. 6 – Image storage:** Storage formats: DICOM: With/without raw data
- optimizarea imaginii in scala de gri	**Conform LOGIQ Fortis Datasheet, pag. 11 – Controls available on "freeze" or recall:** B/M/CrossXBeam mode: Gray map optimization
- amplificare generala pentru modul Doppler spectral	**Conform LOGIQ Fortis Datasheet, pag. 11 – Controls available on "freeze" or recall:** PW mode: Post gain
- amplificare generala pentru modurile Doppler de culoare	**Conform LOGIQ Fortis Datasheet, pag. 11 – Controls available on "freeze" or recall:** Color flow: Overall gain (loops and stills)
- corectia de unghi pentru imaginile Doppler Spectral	**Conform LOGIQ Fortis Datasheet, pag. 11 – Controls available on "freeze" or recall:** PW mode: Angle correct, Quick angle correct, Auto angle correct

- modificarea pozitiei liniei de baza pentru imaginile Doppler spectral	**Conform LOGIQ Fortis Datasheet, pag. 11 – Controls available on "freeze" or recall:** PW mode: Baseline shift
- schimbarea hartilor de gri si de culoare pentru toate modurile de lucru	**Conform LOGIQ Fortis Datasheet, pag. 11 – Controls available on "freeze" or recall:** B/M/CrossXBeam mode: Gray map optimization, Colorized B and M; PW mode: Gray map, Colorized spectrum; Color flow: Color map
Permite stocarea de date in modul inghetat, permanent, in format ciclic, in memoria temporara de tip CINE (memoria imaginilor) si pe memoria de lunga durata	**Conform LOGIQ Fortis Datasheet, pag. 6** – CINE memory/image memory: 1 GB of CINE memory
Informatiile stocate in baza de date prezinta posibilitatea de fi exportate cel putin in urmatoarele formate:	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: On-board database of patient information from past exams"
- format tip DICOM	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: Storage formats: DICOM, Export JPEG, JPEG 2000, WMV (MPEG 4) formats
- tip WMV si tip JPEG	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: Storage formats: DICOM, Export JPEG, JPEG 2000, WMV (MPEG 4) formats
- tip AVI	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: Storage formats: DICOM, Export JPEG, JPEG 2000, WMV (MPEG 4) formats
CARACTERISTICILE MEMORIEI CINE (memoria imaginilor)	
Dispune de spatiu de stocare al datelor in mod ciclic, in memoria imaginilor de peste 950 MB	**Conform LOGIQ Fortis Datasheet, pag. 6** – CINE memory/image memory: 1 GB of CINE memory
Secventele memoriei imaginilor se pot vizualiza in mod dual si in 4 imagini simultan	**Conform LOGIQ Fortis Datasheet, pag. 6** – CINE memory/image memory: Dual Image CINE display, Quad Image CINE display
Fiecare cadru din memoria imaginilor se identifica printr-un numar	**Conform LOGIQ Fortis Datasheet, pag. 6** – CINE memory/image memory: CINE gauge and CINE image number display
Lungimea buclei CINE permite a fi selectata de utilizator	**Conform LOGIQ Fortis Datasheet, pag. 6** – CINE memory/image memory: Selectable CINE sequence for CINE review
COMPATIBILITATEA CU ALTE DISPOZITIVE DE STOCARE:	
Permite atasarea unor dispozitive de stocare gen:	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: Storage devices
USB	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: Storage devices: USB memory stick: 64 MB to 64 GB (for exporting individual images/clips)

CD-R	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: Storage devices: CD-R storage: 700 MB
DVD-R	**Conform LOGIQ Fortis Datasheet, pag. 6** – Image storage: Storage devices: DVD storage: -R (4.7 GB)
POST-PROCESAREA IMAGINII	
Permite functie de marire a imaginii ce este valabila si dupa apasarea butonului de inghetare a imaginii "freeze"	**Conform LOGIQ Fortis Datasheet, pag. 11** – Controls available on “freeze” or recall: Magnification zoom
Imaginile 3D stocate sunt ulterior post-procesate prin ajustarea parametrilor: tip Gain, niveluri de gri	**Conform LOGIQ Fortis Datasheet, pag. 11** – Controls available on “freeze” or recall: 4D: Post gain, Gray map, colorize
Posibilitate de upgrade cu mod de achizitie date de volum 3D/4D, cu posibilitati avansate de afisare si manipulare	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option)**
Ofera posibilitatea afisarii volumelor achizitionate in urmatoarele moduri:	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option)**
- multiplanar	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Visualization modes: Sectional planes (3 section planes perpendicular to each other)
- multiplanar si reconstruit	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Visualization modes: 3D rendering (diverse surface and intensity projection modes)
- tip computer tomograf (multislice)	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Visualization modes: Tomographic ultrasound imaging
Echipamentul permite ca posibilitate de upgrade afisarea simultan pe ecran a peste 8 slice-uri tomoecografice	**Conform LOGIQ Fortis Customer Presentation, pag. 112 – 3D/4D ultrasound: TUI – Tomographic Ultrasound Imaging:** Up to 9 slices, with user selectable distance (min 0.5 mm, step by 0.1 mm) and angle
Distanta minima intre doua slice-uri succesive este 0,5 mm si poate fi reglata in pas de cel putin 0,1 mm	**Conform LOGIQ Fortis Customer Presentation, pag. 112 – 3D/4D ultrasound: TUI – Tomographic Ultrasound Imaging:** Up to 9 slices, with user selectable distance (min 0.5 mm, step by 0.1 mm) and angle
In cazul imaginii reconstruita - 3D, echipamentul permite utilizatorului procesarea acesteia pentru afisarea in urmatoarele modurile:	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Render mode
- maxim pentru vizualizarea doar a structurilor hiperecogene	**Conform LOGIQ Fortis Datasheet, pag. 9** – Real Time 4D (Option): Render mode: Surface texture, surface smooth, max- min- and X-ray (average intensity projection), mix mode of two render modes

- minim pentru vizualizarea doar a structurilor hipoecogene	**Conform LOGIQ Fortis Datasheet, pag. 9** – Real Time 4D (Option): Render mode: Surface texture, surface smooth, max- min- and X-ray (average intensity projection), mix mode of two render modes
- radiologic pentru vizualizarea combinata	**Conform LOGIQ Fortis Datasheet, pag. 9** – Real Time 4D (Option): Render mode: Surface texture, surface smooth, max- min- and X-ray (average intensity projection), mix mode of two render modes
Post-procesarea volumelor reconstruite este posibila prin diverse instrumente software care pot inlatura reconstructiile afectate de artefacte si pe cele ale structurilor ce nu se doresc a fi vizualizate	**Conform LOGIQ Fortis Datasheet, pag. 9** – Real Time 4D (Option): Scalpel: 3D cut tool
Utilizatorul are posibilitatea de a selecta viteza de rotire a imaginiilor 3D	**Conform LOGIQ Fortis Datasheet, pag. 8** – 3D: Allows unlimited rotation and planar translations
Reconstructia 3D este posibila in urma unei singure achizitii de imagini (aparatul prelucreaza scanarile si reda automat imaginea 3D)	**Conform LOGIQ Fortis Datasheet, pag. 8** – 3D: 3D reconstruction from CINE sweep
Structura reconstruita in modul 3D detine grade de libertate nelimitate pentru analiza in orice pozitie	**Conform LOGIQ Fortis Datasheet, pag. 8** – 3D: Allows unlimited rotation and planar translations
Echipamentul permite ajustarea numarului de cadre pe secunda in urma achizitiei unei secvente video ciclice	**Conform LOGIQ Fortis Datasheet, pag. 11** – Controls available on “freeze” or recall: B/M/CrossXBeam mode: Frame average (loops only)
Dupa incetarea prelevarii de date, este posibila autocorectia de unghi in modul pulsat	**Conform LOGIQ Fortis Datasheet, pag. 11** – Controls available on “freeze” or recall: PW mode: Auto angle correct
In modul de post-procesare echipamentul permite inversia spectrului de culoare la Doppler Spectral	**Conform LOGIQ Fortis Datasheet, pag. 11** – Controls available on “freeze” or recall: PW mode: Invert spectral wave form
TEHNOLOGII SI PROGRAME DE EXAMINARE SPECIALE:	
Dispune de posibilitate de upgradare cu un sistem de navigatie care va contine:	**Conform LOGIQ Fortis Datasheet, pag. 9** – Volume navigation (Option)
- emitatorul de camp magnetic	**Conform LOGIQ Fortis Customer Presentation pag. 77** – Volume Navigation, Needle Tip Tracker: Magnetic sensor embedded in the tip of a needle
- senzori de pozitionare	**Conform LOGIQ Fortis Datasheet, pag. 9** – Volume navigation (Option): Position markers
- ghiduri de navigatie si biopsie	**Conform LOGIQ Fortis Customer Presentation pag. 77** – Volume Navigation, Needle Tip Tracker: Guide in-plane or out-of-plane biopsies
- ac cu senzor incorporat	**Conform LOGIQ Fortis Datasheet, pag. 9** – Volume navigation (Option): Needle tip tracking

- sistemul de navigatie sa poata functiona cu minimum 8 sonde de diferite tipuri	**Conform LOGIQ Fortis Datasheet, pag. 9** – Volume navigation (Option): Available on the following probes: C1-6VN-D, C2-9VN-D, C2-7VN-D, C3-10-D, L2-9VN-D, ML6-15-D, IC5-9-D, L8-18i-D, M5Sc-D
In cazul imaginilor suprapuse, echipamentul permite reglarea nivelului de transparenta al imaginilor analizate	**Conform LOGIQ Fortis – Basic User Manual, pag. 13-305 – Volume Navigation:** Inner Alpha/Margin Alpha: Adjust transparency of main area and margin in percent i.e. between 0 (= only ultrasound image) and 100 (= only marker/margin color).
Prezinta posibilitatea de utilizare a navigatiei cu markere GPS pentru a urmari regiunea anatomica de interes	**Conform LOGIQ Fortis Customer Presentation pag. 76 – Volume Navigation, 3D GPS:** Spherical markers for tracking anatomy, including margins
Modulul de navigatie este disponibil cel putin pe modurile de lucru tip B, tip Doppler Color si tip Contrast	**Conform LOGIQ Fortis – Basic User Manual, pag. 13-262 – Volume Navigation:** V Nav is available in B-Mode, Color Flow, Elastography, PDI, and Contrast Modes
In cazul modului de navigatie de volum prezinta posibilitate de urmarire a acului de biopsie	**Conform LOGIQ Fortis Datasheet, pag. 9 – Volume navigation (Option):** Virtual tracking
Urmarirea acului de biopsie se realizeaza pe baza unui senzor electromagnetic plasat in varful acului	**Conform LOGIQ Fortis Customer Presentation pag. 77 – Volume Navigation, Needle Tip Tracker:** Magnetic sensor embedded in the tip of a needle
Senzorul electromagnetic este reutilizabil	**Conform LOGIQ Fortis Customer Presentation pag. 77 – Volume Navigation, Needle Tip Tracker:** Magnetic sensor embedded in the tip of a needle, Reusable sensor helps you track the needle tip as you navigate through the body
Modul de navigare ofera o virtualizare a traiectoriei acului inainte de inceperea procedurii	**Conform LOGIQ Fortis Datasheet, pag. 9 – Volume navigation (Option):** Virtual tracking
Pe parcursul procedurii de navigatie modul de urmarire are posibilitatea de a calcula automat traiectoria optima a acului in functie de pozitionarea senzorului electromagnetic	**Conform LOGIQ Fortis Customer Presentation pag. 77 – Volume Navigation, Needle Tip Tracker:** View a live display of position and orientation, Plan and monitor interventional procedures with real-time fused data
Dispune de posibilitate de upgradare cu mod de masurarea cantitativa si calitativa in timp real a elasticitatii structurii examinate prin tehnologia de tip „2D Shear Wave", avand compresie automata. Permite vizualizare si cuantificare a informatiei intr-o regiune de interes ce prezinta posibilitatea de ajustare a marimii ferestrei de catre utilizator precum si a adancimii de evaluare. Aceasta tehnologie este conceputa pentru estimarea cat mai precisa a fibrozei si elasticitatii tesutului si indeplineste cel putin urmatoarele criterii:	**Conform LOGIQ Fortis Datasheet, pag. 9 – Shear Wave Elastography (Option)** **Conform LOGIQ Fortis Customer Presentation pag. 102 – Shear Wave elastography:** Focused burst of acoustic energy to perform tissue deformation through a comb-push excitation, Focus: Chronic liver disease, oncology **Conform LOGIQ Fortis Customer Presentation pag. 106 – Elastography, 2D Shear Wave:** Adjustable Color Box and ROI depth and size

Tehnologia este disponibila atat pe transductor convex cat si pe transductor liniar	**Conform LOGIQ Fortis Datasheet, pag. 9 – Shear Wave Elastography (Option):** Available on the following probes: C1-6-D, C1-6VN-D, IC5-9-D, L2-9-D, L2-9VN-D,L3-12D, ML6-15-D, L8-18D
Masuratoarile sunt exprimate in Kpa si in m/s	**Conform LOGIQ Fortis Datasheet, pag. 9 – Shear Wave Elastography (Option):** User programmable measurement display in kPa and meters per second
Utilizatorului i se ofera posibilitatea de a selecta modul de vizualizare preferat: afisare imagine duala si imagine unica	**Conform LOGIQ Fortis Datasheet, pag. 9 – Shear Wave Elastography (Option):** Single and dual view display
In modul de lucru tip „2D Shear Wave" echipamentul detine capabilitatea de a reimprospata permanent cadrele	**Conform LOGIQ Fortis Customer Presentation pag. 106 – Elastography, 2D Shear Wave:** Fast acquisition time to reduce motion artifacts
Plasare automata a masuratorii si a regiunii de interes in vederea optimizarii fluxului de lucru	**Conform LOGIQ Fortis Customer Presentation pag. 106 – Elastography, 2D Shear Wave:** Auto sequencing feature for an automatic placement of measurement ROI within image
Permite efectuarea de masuratori multiple in zona de interes in vederea reducerii numarului de achizitii	**Conform LOGIQ Fortis Customer Presentation pag. 106 – Elastography, 2D Shear Wave:** Multiple measurements within a single shear wave image
Pentru o evaluare si corelare simultana a informatiilor, tehnologia Shear Wave poate fi folosita si intr-un modul de Navigatie Volumetrica in fuziunea ecografiei in timp real cu examinarile PET CT, RMN, CT, etc.	**Conform LOGIQ Fortis Customer Presentation pag. 70 – Elastography, 2D Shear Wave:** Can be any modality as CT, MR, PET/CT, CBCT, and 3D CEUS **Conform LOGIQ Fortis Customer Presentation pag. 106 – Elastography, 2D Shear Wave:** Working in combination with Volume Navigation and Needle Tracking Comprehensive tool for liver disease management
Posibilitate de upgrade cu modul software de cuantificare a steatozei pentru identificarea si monitorizarea pacientilor care sa dispuna de indicator de calitate, harti de atenuare, posibilitatea de efectuare a masuratorilor in mod automat cu afisarea valorilor de referinta. Modulul sa fie disponibil pe sonde convexe.	**Conform LOGIQ Fortis Datasheet, pag. 10** – UGAP (Option): Available on the following probes: C1-6-D, C1-6VN-D, C2-9D, C2-9VN-D **Conform LOGIQ Fortis Customer Presentation pag. 109** – Ultrasound-Guided Attenuation Parameter (UGAP), Quantifies liver steatosis to aid in early identification and monitoring of patients with NAFLD, NASH or ASH: Quality Indicator and user selectable color maps, Attenuation Map, Multiple measurements within an image, Auto measurement feature for ROI placement, Dual or single display option, Measurements available in Attenuation Rate or, Attentuation Coefficient, Mean and IQR display
Posibilitate de upgrade cu modul ce permite combinarea elastografiei de tip Shear Wave cu modulul de	**Conform LOGIQ Fortis Datasheet, pag. 4 – Options:** Hepatic assistant **Conform LOGIQ Fortis Customer Presentation**

cuantificare a steatozei, printr-o simpla apasare a unui buton.	**pag. 161 – Hepatic Assistant:** Enables clinicians to combine 2D Shear Wave Elastography and Ultrasound-Guided Attenuation Parameter (UGAP) in a single exam with just the push of a button.
Dispune de mod de analiza ce ofera posibilitatea de evaluare a elasticitatii tesuturilor prin aplicarea unei presiuni mecanice de catre utilizator	**Conform LOGIQ Fortis Datasheet, pag. 10** – Strain Elastography (Option)
Echipamentul detine software de elastografie pe sondele liniare si pe sondele convexe si endocavitare	**Conform LOGIQ Fortis Customer Presentation pag. 103** – Elastography, Strain imaging: Strain imaging technology requiring a light manual compression or vessel pulsation to perform tissue deformation. "
Modul de lucru pentru elastografie prezinta urmatoarele caracteristici:	
- afiseaza pe ecran o imagine in mod dual	**Conform LOGIQ Fortis Customer Presentation pag. 103** – Elastography, Strain imaging: Dual measurements
- permite configurarea hartilor de culoare de catre utilizator	**Conform LOGIQ Fortis Customer Presentation pag. 103** – Elastography, Strain imaging: User selectable color maps
- permite analiza memoriei imaginii cu eliminarea frame-urilor in care procedura nu a fost aplicata corect	**Conform LOGIQ Fortis Customer Presentation pag. 103** – Elastography, Strain imaging: High sensitivity and persistence
Analiza elastografiei prezinta posibilitatea de a fi vizualizata cel putin in urmatoarele moduri:	**Conform LOGIQ Fortis Customer Presentation pag. 103 – Elastography, Strain imaging: Photo**
- pe ecran complet	**Conform LOGIQ Fortis Customer Presentation pag. 103 – Elastography, Strain imaging: Photo**
- 2 imagini simultane (2D si elastografie)	**Conform LOGIQ Fortis Customer Presentation pag. 103 – Elastography, Strain imaging: Photo**
Dispune de modul de cuantificare elastografica	**Conform LOGIQ Fortis Datasheet, pag. 4 – Options:** Elastography quantification
Dispune de posibilitate de upgradare cu mod pentru ecografie de contrast hibrid avand urmatoarele caracteristici:	**Conform LOGIQ Fortis Datasheet, pag. 8 – Coded contrast imaging (Option)**
- echipamentul permite afisarea informatiei in mod dual screen cu contorizare separata pe fiecare afisaj	**Conform LOGIQ Fortis Datasheet, pag. 8 – Coded contrast imaging (Option):** 2 contrast timers
Ecografia de contrast prezinta posibilitatea de a regla cel putin urmatorii parametri:	
- timp (updatare: 0.05 – 10 sec)	**Conform LOGIQ Fortis Datasheet, pag. 8 – Coded contrast imaging (Option):** Timed updates: 0.05 – 10 seconds

- mod amplificare maxima	**Conform LOGIQ Fortis Datasheet, pag. 8 – Coded contrast imaging (Option):** Maximum enhance mode
- procesarea informatiei si pe date brute	**Conform LOGIQ Fortis Customer Presentation pag. 65 – Contrast ultrasound, Time Intensity Curve (TIC):** Raw data processing for Contrast uptake
- Peste 6 regiuni de interes selectabile	**Conform LOGIQ Fortis Customer Presentation pag. 65 – Contrast ultrasound, Time Intensity Curve (TIC):** Up to 8 selectable ROIs, Up to 10 parameters
- analiza a peste 9 parametri	**Conform LOGIQ Fortis Customer Presentation pag. 65 – Contrast ultrasound, Time Intensity Curve (TIC):** Up to 8 selectable ROIs, Up to 10 parameters
- regiunea de interes poate fi definita elipsoidal sau la alegerea utilizatorului	**Conform LOGIQ Fortis Customer Presentation pag. 65 – Contrast ultrasound, Time Intensity Curve (TIC):** Ellipsoid or manual ROI tracing
Permite analiza cantitativa a curbelor de evolutie a indicelui termic in cadrul programului de ecografie cu substanta de contrast	**Conform LOGIQ Fortis Datasheet, pag. 8 – Coded contrast imaging (Option):** Time intensity curve (TIC) analysis
Posibilitate de upgrade cu tehnică ce oferă informații despre „timpul de sosire” al agentului de contrast în culori prin procesarea buclelor cine cu valoare prag predefinită pentru fiecare pixel.	**Conform LOGIQ Fortis Datasheet, pag. 8 – Coded contrast imaging (Option):** Parametric imaging **Conform LOGIQ Fortis Customer Presentation pag. 65 – Contrast ultrasound, Parametric analysis:** Arrival time analysis of contrast-enhanced raw data cine clips
Dispune de posibilitate de upgradare cu analiza cantitativa Doppler Color si Power	**Conform LOGIQ Fortis Datasheet, pag. 10 – Quantitative flow analysis (Option):** Available in color and power Doppler
Dispune de posibilitate de upgradare cu soft ce permite vizualizarea acului de biopsie in timpul procedurilor interventionale. Acest instrument prezinta urmatoarele caracteristici:	**Conform LOGIQ Fortis Customer Presentation pag. 101 – B-Steer+:** B-Steer+ feature enables enhanced visualization of the needles structure during interventional procedures, helping improve user confidence.
- posibilitatea selectarii a 12 unghiuri de inclinare (cate 6 pentru fiecare directie)	**Conform LOGIQ Fortis Customer Presentation pag. 101 – B-Steer+:** Up to 12 selectable steering angles available (six each direction)
- posibilitatea selectarii separate a gain-ului pentru acul de biopsie	**Conform LOGIQ Fortis Customer Presentation pag. 101 – B-Steer+:** Separate gain control for needle refleciton

- disponibil pe traductorii de tip liniar, liniar matricial, liniar Hockey Stick, liniar intraoperator si liniar volumetric	**Conform LOGIQ Fortis Customer Presentation pag. 101 – B-Steer+:** Available on all linear transducers
- activarea softului printr-o singura apasare de buton	**Conform LOGIQ Fortis Customer Presentation pag. 101 – B-Steer+:** Quick one-button operation
Prezenta tehnologie de afisare a intensitatii fluxurilor sangvine, independenta de unghiul de interogare a razei ultrasunetelor, in vederea vizualizarii cu exactitate a informatie hemodinamice. Aceasta tehnologie va dispune de rezolutie spatiala similara cu aceea a scalei modului 2D si permite afisarea informatiei pe intreaga suprafata de scanare.	**Conform LOGIQ Fortis Datasheet, pag. 8 – B-Flow (Option)** **Conform LOGIQ Fortis Customer Presentation pag. 87 – B-Flow, Direct hemodynamic visualization:** Visualize blood flow and depict the hemodynamic profile without unwanted signals from surrounding tissue and with increase sensitivity and resolution compared to Color Doppler. B-Flow Imaging: Innovative non-Doppler technology, Direct visualization of blood reflectors
- metoda conceputa pentru studiul si analiza stenozelor vasculare, hematoamelor, trombozelor, fistulei AV, activitatii nodulilor, perfuziei renale, morfologiei plagilor arteriale, turbulentelor arterei carotide si a eventualelor sinoase, diferentierii vaselor cu fluxuri mici, tiroida etc.	**Conform LOGIQ Fortis Datasheet, pag. 8 – B-Flow (Option)** **Conform LOGIQ Fortis Customer Presentation pag. 87 – B-Flow, Direct hemodynamic visualization:** Visualize blood flow and depict the hemodynamic profile without unwanted signals from surrounding tissue and with increase sensitivity and resolution compared to Color Doppler. B-Flow Imaging: Innovative non-Doppler technology, Direct visualization of blood reflectors
- evidentiaza cu intensitati diferite vasele de sange pentru o mai buna vizualizare si o rezolutie superioara	**Conform LOGIQ Fortis Datasheet, pag. 8 – B-Flow (Option)** **Conform LOGIQ Fortis Customer Presentation pag. 88 – B-Flow, Direct hemodynamic visualization:** Display real hemodynamics, Direct visualization of blood reflectors
- afiseaza imagine in mod dual	**Conform LOGIQ Fortis Customer Presentation pag. 89 – B-Flow:** B-Flow Dual View Spleen, C2-9-D
- afiseaza imagine in mod hibrid (imagine in mod B si imagine cu mod ce pune in evidenta microvascularizatia) cu multiple harti hibride disponibile	**Conform LOGIQ Fortis Customer Presentation pag. 89 – B-Flow:** B-Flow Hybrid Visualization of Kidney, C2-9-D
- este disponibil pe traductor abdominal	**Conform LOGIQ Fortis Datasheet, pag. 8 – B-Flow (Option):** Available on the following probes: C1-6-D, C1-6VN-D, C2-7-D, C2-7VN-D, C2-9-D,C2-9VN-D, C3-10-D, L2-9-D, L2-9VN-D, L3-12-D, ML6-15-D,M5Sc-D, L8-18i-D, L6-24D
- este disponibil pe traductor liniar si traductor liniar matricial	**Conform LOGIQ Fortis Datasheet, pag. 8 – B-Flow (Option):** Available on the following probes: C1-6-D, C1-6VN-D, C2-7-D, C2-7VN-D, C2-9-

	D,C2-9VN-D, C3-10-D, L2-9-D, L2-9VN-D, L3-12-D, ML6-15-D,M5Sc-D, L8-18i-D, L6-24D
Dispune de posibilitate de upgradare cu modul de calcul automat si asistat al volumelor bazate pe achizitia de 3D cu urmatoarele caracteristici:	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Automated volume calculation – VOCAL II
- definirea marginilor: automata, semiautomata sau manuala	**Conform LOGIQ Fortis Customer Presentation pag. 114 – 3D/4D ultrasound, VOCAL:** Manual, semi automatic or automatic borders definition
- masuratori de baza ca: lungimi, unghiuri si arii	**Conform LOGIQ Fortis Customer Presentation pag. 114 – 3D/4D ultrasound, VOCAL:**Basic measurements as length, angle and area
- corectii de contur	**Conform LOGIQ Fortis Customer Presentation pag. 114 – 3D/4D ultrasound, VOCAL:**Easy corrections and contour modifications
Dispune de posibilitate de upgradare cu modul de lucru pentru imagini tomoecografice cu urmatoarele caracteristici:	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Tomographic ultrasound imaging
Peste 8 campuri (slice-uri) paralele	**Conform LOGIQ Fortis Customer Presentation pag. 112 – 3D/4D ultrasound, TUI – Tomographic Ultrasound Imaging:** Up to 9 slices, with user selectable distance (min 0.5 mm, step by 0.1 mm) and angle
intervalul de distanta dintre slice-uri sa poata fi selectat de utilizator	**Conform LOGIQ Fortis Customer Presentation pag. 112 – 3D/4D ultrasound, TUI – Tomographic Ultrasound Imaging:** Up to 9 slices, with user selectable distance (min 0.5 mm, step by 0.1 mm) and angle
distanta minima dintre slice-uri poate fi de: 0.5 mm	**Conform LOGIQ Fortis Customer Presentation pag. 112 – 3D/4D ultrasound, TUI – Tomographic Ultrasound Imaging:** Up to 9 slices, with user selectable distance (min 0.5 mm, step by 0.1 mm) and angle
navigarea intre slice-urile paralele se poate face in pasi de 0.1 mm	**Conform LOGIQ Fortis Customer Presentation pag. 112 – 3D/4D ultrasound, TUI – Tomographic Ultrasound Imaging:** Up to 9 slices, with user selectable distance (min 0.5 mm, step by 0.1 mm) and angle
Dispune de posibilitate de upgradare cu tehnologie de achizitie volumetrică ce îi permite utilizatorului să obţină şi să vizualizeze cu claritate zona anatomică de interes în orice plan, prin trasarea unei linii, curbe, urme fără limite de ortogonalitate a planului	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Visualization modes: Omniview
Dispune de posibilitatea de upgradarea cu tehnica de vizualizare in mod 3D a structurilor interne prin modificarea transparentei si a pozitiei sursei de lumina	**Conform LOGIQ Fortis Datasheet, pag. 9 – Real Time 4D (Option):** Render mode: Hdlive

Dispune de posibilitatea de upgradare cu modul de obtinere a imaginilor tridimensionale ale cordului fetal in modul standard, fara artefacte de miscare, cu ajutorul unui program specializat (STIC = Spatio-Temporal Image Correlation).	**Conform LOGIQ Fortis Customer Presentation pag. 166 – 3D/4D ultrasound, STIC:** Spatio-Temporal Image Correlation (STIC) captures one fetal heart cycle in 3D cine.
Acest modul pemite lucrul atat cu mod Doppler Color cat si cu mod Doppler Power	**Conform LOGIQ Fortis Customer Presentation pag. 166 – 3D/4D ultrasound, STIC:** Use with Color Doppler or Power Doppler modes
Posibilitate de upgradare cu modul care permite masurarea translucentei nucale si a translucentei intracraniane	**Conform LOGIQ Fortis Datasheet, pag. 4 – Options:** SonoNT SonoIT
Dispune de posibilitate de upgradare cu modul de detectare si masurare automata a leziunilor de la nivelul sanului	**Conform LOGIQ Fortis Customer Presentation pag. 135 – Measure Assistant, Designed to work in breast exams:** A few simple steps to assist the user with breast measurements
Dispune de posibilitate de upgradare cu modul de masurare automata a urmatorilor parametri: circumferinta abdominala, diametriul biparietal, circumferinta craniului si lungimea femurului.	**Conform LOGIQ Fortis Customer Presentation pag. 137 – Measure Assistant, Designed to work in OB exams:** Measurement auto applied: FL, HC/BPD, AC
Dispune de posibilitate de upgradare cu modul de asistare a scanarii in vederea imbunatatirii fluxului de lucru permitand crearea de protocoale standardizate	**Conform LOGIQ Fortis Datasheet, pag. 9 – Scan assistant (Option):** Factory programs, User-defined programs, Steps include image annotations, mode transitions, basic imaging controls, and measurement initiation
Acest modul ofera posibilitatea de initiere a masuratorilor, inclinarea automata a planului in modul Doppler Color, inserare automata a comentariilor, etc., permitand astfel utilizatorului de a se concentra asupra examinarii	**Conform LOGIQ Fortis Customer Presentation pag. 134 – Scan Assistant, A system that thinks the way you do:** Assists the user with customizable automations Initiates and completes required measurements, Automatically steers color Doppler, Automatically sets up imaging controls and modes, Automatically inserts comments
Dispune de posibilitate de upgradare cu tehnologie de achizitie in volum in vederea redarii si vizualizarii cu claritate a zonei anatomice de interes, indiferent de planul de afisare a imaginii. Aceasta tehnologie de achizitie in volum ajuta la imbunatatirea contrastului si rezolutiei in modul B	**Conform LOGIQ Fortis Customer Presentation pag. 113 – 3D/4D ultrasound, VCI – Volume Contrast Imaging:** VCI is a volume post processing technique which helps improve B-Mode contrast resolution and speckle suppression. Helps improve assessment of lesions size, margins and internal structures for comprehensive patient management.
Dispune de posibilitate de upgradare cu Imagistica de Velocitate a Tesutului cu analiza cantitativa	**Conform LOGIQ Fortis Datasheet, pag. 10 – TVI (Option):** Myocardial Doppler imaging with color overlay on tissue image
Dispune de posibilitate de upgradare cu pachet ultraspecializat de masurare la nivelul sanului ce permite etichetarea, masurarea si descrierea cu usurinta a leziunilor sanului, precum si localizarea leziunilor si a nodulilor limfatici.	**Conform LOGIQ Fortis Datasheet, pag. 9 – Breast productivity package:** Auto measurement, Worksheet summary includes measurements and locations for lesions and lymph nodes **Conform LOGIQ Fortis Customer Presentation**

	pag. 136 – Breast Productivity, Measurement package: A dedicated breast-specific measurement package that allows users to: Make labeling, measuring and describing lesion easy, Leverage the BI-RADS® lexicon criteria/assessment, Organizes multiple measurements into a convenient worksheet , Send results via DICOM® SR
Acest pachet include raportare si documentare de clasificare conform standardizarii BI-RADS	**Conform LOGIQ Fortis Datasheet, pag. 9 – Breast productivity package:** BI-RADS® assessment
Dispune de posibilitate de upgradare cu pachet de masurare si localizare a nodulilor limfatici cat si a nodulilor de la nivelul tiroidei si paratiroidei	**Conform LOGIQ Fortis Datasheet, pag. 9 – Thyroid productivity package:** Auto measurement, Worksheet summary includes measurements and locations for nodule, parathyroid, and lymph node
Dispune de posibilitate de upgradare cu modul avansat de ecografie de stres cu protocoale farmacologice şi de exerciţii prezentand urmatoarele caraceristici:	**Conform LOGIQ Fortis Datasheet, pag. 10 – Stress echo (Option):** Advanced and flexible stress echo examination capabilities, Provides exercise and pharmacological protocol templates
- dispune de cel putin 5 protocoale de standard de lucru	**Conform LOGIQ Fortis Datasheet, pag. 10 – Stress echo (Option):** 6 default templates
- permite crearea de protocoale noi in functie de preferintele utilizatorului si se pot modifica cele standard existente	**Conform LOGIQ Fortis Datasheet, pag. 10 – Stress echo (Option):** Template editor for user configuration of existing templates or creation of new templates,
- afisarea rezultatului este prezentata sub forma de "ochi-de-bou" (bulls-eye) sau segmental.	**Conform LOGIQ Fortis Datasheet, pag. 10 – Stress echo (Option):** Wall motion scoring (bulls-eye and segmental)
- sistem inteligent pentru setarea automata a parametrilor de scanare precum: geometria, frecventa, amplificarea, etc.	**Conform LOGIQ Fortis Datasheet, pag. 10 – Stress echo (Option):** Smart stress: Automatically set up various scanning parameters (e.g. geometry, frequency, gain) according to same projection on previous level
Dispune de posibilitate de upgradare cu instrument specializat ce permite masurarea semi-automata, evaluarea si cuantificarea contractiilor, atat la nivel segmental cat si la nivel global, a peretului longitudinal al ventriculului stang folosind metoda speckle tracking	**Conform LOGIQ Fortis Datasheet, pag. 10 – Cardiac AFI (Option):** Allows assessment of the complete left ventricle with all segments at a glance by combining three longitudinal views into one comprehensive bulls-eye view, 2D strain-based data moves into clinical practice
Pentru calculul deformarii tesutului miocardic echipamentul dispune de posibilitate de upgradare cu instrumente de masurare semi-automate a fractiei de ejectie	**Conform LOGIQ Fortis Datasheet, pag. 10 – Auto EF (Option):** Allows semi-automatic measurement of the global EF (Ejection Fraction)
Dispune de posibilitate de upgradare cu mod ce calculeaza grosimea intimei media bazandu-se pe	**Conform LOGIQ Fortis Datasheet, pag. 4 – Options:** Auto IMT

detectarea automata a conturului dintr-o regiune de interes de-a lungul peretului vasului.	
Dispune de posibilitate de upgradare cu pachet automat de editare a rapoartelor ce poate include sabloane standard si/sau customizabile la preferintele utilizatorului	**Conform LOGIQ Fortis Datasheet, pag. 6 – Report writer (Option):** On-board reporting package automates report writing, Customizable templates
Dispune de posibilitate de upgradare cu baterie dedicata si conceputa special in vederea scanarii offline pentru cel putin o ora atunci cand echipamentul nu este conectat la sursa de curent electric.	**Conform LOGIQ Fortis Datasheet, pag. 4 – Options:** Power assistant and scan on battery
Posibilitatea de upgradare cu metoda de stocare a datelor in Cloud, serviciu destinat sa faciliteze distribuirea informatiilor medicale cu personalul medical sau pacientii	**Conform LOGIQ Fortis Datasheet, pag. 4 – Options:** Tricefy®
Posibilitate de upgrade cu program care asigura o securizare suplimentară a datelor și a aplicațiilor	**Conform LOGIQ Fortis Datasheet, pag. 4 – Options:** Advanced privacy and security (vulnerability scan)
Sitemul dispune de posibilitate de upgrade cu mod ce permite operarea urmatoarelor funcții de pe o tableta sau telefon cu ajutorul unei aplicatii dedicate instalata pe acestea: inghețarea imaginii ('freeze'), printare, selectarea regiunii de interes, reglarea adâncimii de scanare, ajustarea amplificarii, selectarea vizualizării in mod dual	**Conform LOGIQ Fortis Datasheet, pag. 4 – Peripheral options:** LOGIQ smart device apps: Photo Assistant, Remote Control **Conform LOGIQ Fortis Customer Presentation, pag. 130 – LOGIQ™ apps, Remote Control:** Remotely operate the system from tablet or phone that that has LOGIQ Smart app loaded, Focused on ergonomics, Includes: Major modes, Freeze/print, Depth, Gain, ROI placement, Dual image
Pentru urmarirea riguroasa a evolutiei planului de tratament, sistemul dispune de posibilitatea opțională de incarcare in ecograf a pozelor efectuate cu tableta/telefonul pentru investigarea concomitenta a imaginilor ecografice cu pozele zonelor de suprafata cu scopul de a ține sub control leziunile tegumentare cauzate de intervenții, infecții sau alte anomalii aparute la nivelul superficial sau de a corela anumite anomalii ale imaginii achiziționate cu ajutorul ecografului cu defectele de structura vizibile.	**Conform LOGIQ Fortis Datasheet, pag. 4 – Peripheral options:** LOGIQ smart device apps: Photo Assistant, Remote Control **Conform LOGIQ Fortis Customer Presentation, pag. 130 – LOGIQ™ apps, Photo Assistant:** A picture is worth a 1000 words, Photograph relevant anatomy and include photos with the clinical images, Provides value context for documentation and comparison after a procedure, Utilizes Android™ tablet or phone, Bar code reader
CONECTIVITATE SI TRANSFER DE DATE	
Prezinta posibilitatea de conectare la retea wireless si LAN	**Conform LOGIQ Fortis Datasheet, pag. 4** – Options: DVR
Posibilitate de conexiune DVI-D si HDMI	**Conform LOGIQ Fortis Datasheet, pag. 15** – External Inputs and outputs (not including on-board peripherals): HDMI"
Detine MPPS (ofera posibilitatea de efectuare a procedurii pas cu pas – masurare precisa a distantei, ariei si volumului)	**Conform LOGIQ Fortis Datasheet, pag. 6** – Connectivity: Modality performed procedure step (MPPS)

Posibilitate de conexiune pentru transferul datelor minim USB – porturi multiple disponibile	**Conform LOGIQ Fortis Datasheet, pag. 15** – External Inputs and outputs (not including on-board peripherals): Multiple USB 3.0 ports
Dispunde de posibilitate de upgradare cu modul pentru monitorizarea semnalului ECG , permițând ajustarea amplificarii ECG.	**Conform LOGIQ Fortis Datasheet, pag. 6 – Physiological input panel (Option)**: Physiological input: ECG, 1 channel
Acces pentru personalul medical la instrumente de educatie continua, adaptate platformei de lucru a sistemului, cu instrumente gratuite, accesul la cursuri online, ghiduri si recomandari ale producatorului in vederea optimizarii fluxului de lucru cu echipamentul, pentru modurile de lucru ale acestuia, precum si acces la ultimile noutati si publicatii internationale de profil.	**Conform LOGIQ Fortis Customer Presentation pag. 223** – LOGIQ™ Club users' community, Education highlights
B) CONFIGURATIE DE LIVRARE:	
B.1) Consola ecografica multidisciplinara, de inalta performanta care sa indeplineasca toate cerintele de la punctul **A)**	**DA va fi inclus**
Optiuni incluse: Elastografie compresiva, Elastografie Cuantificata, Mod de afisare a intensitatii fluxurilor sangvine, independenta de unghiul de interogare a razei ultrasunetelor.	**DA va fi inclus**
B.2) Traductori:	
1 bucata sonda convexa cu tehnologie Single Cristal/ Matrix, XDClear vederea obtinerii de imagini cu rezolutie superioara, conceputa pentru aplicatii abdominale, obstetrice, ginecologice, vascular cu urmatoarele caracteristici:	**Conform LOGIQ Fortis Datasheet, pag. 14 – Probes: C1-6-D, XDclear™ convex probe:** Applications: abdomen, OB/GYN, pediatric, peripheral vascular, general musculoskeletal
- banda de frecvente de lucru acopera minimum intervalul: 1-5.8 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 2 – CONVEX: C1-6-D:** Bandwidth: 1 – 6 MHz
- camp vizual de peste 78 grade	**Conform LOGIQ Fortis Probe Guide, pag. 2 – CONVEX: C1-6-D:** FOV: 80º
- compatibila cu sistemul de navigatie volumetrica	**Conform LOGIQ Fortis Probe Guide, pag. 2 – CONVEX: C1-6-D:** Volume Navigation: Yes
- tehnologie cu peste 190 de cristale	**Conform LOGIQ Fortis Spec Sheet, pag. 16 – C1-6-D, XDclear™ convex probe:** Number of elements: 192
- permite lucrul cu 4 frecvente diferite in transmisie pentru modul B	**Conform LOGIQ Fortis Spec Sheet, pag. 16 – C1-6-D, XDclear™ convex probe:** B-Mode frequency: 2.0, 2.5, 3.0, 4.0 MHz
- permite lucrul cu 5 frecvente diferite in transmisie pentru modul Doppler Color	**Conform LOGIQ Fortis Spec Sheet, pag. 16 – C1-6-D, XDclear™ convex probe:** Color Doppler frequency: 1.8, 2.1, 2.5, 2.8, 3.0 MHz

- permite lucrul cu 6 frecvente diferite in transmisie pentru modul de lucru cu armonice codate	**Conform LOGIQ Fortis Spec Sheet, pag. 16 – C1-6-D, XDclear™ convex probe:** Harmonic frequency: 1.5, 2.5, 3.0, 4.5, 6.0, 6.5 MHz
- permite lucrul cu cel putin 4 frecvente diferite in transmisie pentru modul de lucru Doppler cu unda pulsatia	**Conform LOGIQ Fortis Spec Sheet, pag. 16 – C1-6-D, XDclear™ convex probe:** PW Doppler frequency: 1.7, 2.1, 2.5, 3.6 MHz
- amprenta de minim 66 x 10 mm	**Conform LOGIQ Fortis Spec Sheet, pag. 16 – C1-6-D, XDclear™ convex probe:** Physical foot print: 67 x 11 mm
- poate dispune de upgrade cu kit de biopsie multiangular	**Conform LOGIQ Fortis Probe Guide, pag. 2 – CONVEX: C1-6-D:** Biopsy Guide: Multi-angle disposable with a reusable bracket
1 bucata sonda micro-convexa intra-cavitara pentru aplicatii obstretice, ginecologice si urologice ce prezinta minimum urmatoarele cerinte:	**Conform LOGIQ Fortis Datasheet, pag. 14 – Probes: IC5-9-D, micro convex probe:** Applications: OB/GYN, urology
- banda de frecvente de lucru acopera minimum intervalul: 3 - 9.5 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 2 – CONVEX: IC5-9-D:** Bandwidth: 3 – 10 MHz
- camp vizual de peste 175 grade	**Conform LOGIQ Fortis Probe Guide, pag. 2 – CONVEX: IC5-9-D:** FOV: 180º
- tehnologie cu peste 190 de cristale	**Conform LOGIQ Fortis Probe Guide, pag. 2 – CONVEX: IC5-9-D:** Volume Navigation: Yes
- permite lucrul cu 6 frecvente diferite in transmisie pentru modul B	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – CONVEX: IC5-9-D:** Number of elements: 192
- permite lucrul cu 3 frecvente diferite in transmisie pentru modul Doppler Color	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – CONVEX: IC5-9-D:** B-Mode frequency: 4.5, 5.0, 5.5, 6.0, 7.0, 8.0 MHz
- permite lucrul cu cel putin 4 frecvente diferite in transmisie pentru modul cu armonice codate	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – CONVEX: IC5-9-D:** Color Doppler frequency: 4.6, 5.9, 6.7 MHz
- permite lucrul cu cel putin 3 frecvente diferite in transmisie pentru modul Doppler cu unda pulsatila	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – CONVEX: IC5-9-D:** Harmonic frequency: 6.0, 6.5, 7.0, 9.0 MHz
- poate dispune de upgrade cu kit de biopsie	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – CONVEX: IC5-9-D:** PW Doppler frequency: 3.6, 4.2, 5.0 MHz
1 bucata sonda liniara cu tehnologie Single Cristal/ Matrix, XDClear in vederea obtinerii de imagini cu rezolutie superioara, conceputa pentru aplicatii abdominale, pediatrice, ale sistemului vascular si a partilor moi ce prezinta urmatoarele caracteristici:	**Conform LOGIQ Fortis Datasheet, pag. 14 – Probes: L2-9-D, XDclear linear probe:** Applications: peripheral vascular, small parts, pediatric, abdomen, OB/GYN, general musculoskeletal,

	superficial musculoskeletal, neonatal, neonatal transcranial
- banda de frecvente de lucru acopera minim intervalul: 2 - 9.8 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 2 – LINEAR: L2-9-D:** Bandwidth: 2 – 10 MHz
- compatibila cu sistemul de navigatie volumetrica	**Conform LOGIQ Fortis Probe Guide, pag. 2 – LINEAR: L2-9-D:** Volume Navigation: Yes
- camp vizual de peste 42 mm	**Conform LOGIQ Fortis Probe Guide, pag. 2 – LINEAR: L2-9-D:** FOV: 44 mm
- tehnologie cu peste 190 de cristale	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – L2-9-D, XDclear linear probe:** Number of elements: 192
- permite lucrul cu 4 frecvente diferite in transmisie pentru modul B	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – L2-9-D, XDclear linear probe:** B-Mode frequency: 4.0, 4.5, 5.0, 6.0, 7.0 MHz
- permite lucrul cu 4 frecvente diferite in transmisie pentru modul Doppler Color	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – L2-9-D, XDclear linear probe:** Color Doppler frequency: 3.1, 4.0, 4.6, 5.3 MHz
- poate dispune de upgrade cu kit de biopsie multiangular	**Conform LOGIQ Fortis Probe Guide, pag. 2 – LINEAR: L2-9-D:** Biopsy Guide: Multi-angle disposable with a reusable bracket
1 bucata sonda liniara pentru aplicatii pediatrice, musculoscheletale si tiroida ce prezinta urmatoarele caracteristici:	**Conform LOGIQ Fortis Datasheet, pag. 14 – Probes: L6-24-D, linear probe:** Applications: general musculoskeletal, superficial musculoskeletal, pediatrics, thyroid
- banda de frecvente de lucru acopera minimum intervalul: 6.2 - 20 MHz	**Conform LOGIQ Fortis Probe Guide, pag. 2 – LINEAR: L6-24-D:** Bandwidth: 6 – 20 MHz
- camp vizual de peste 25 mm	**Conform LOGIQ Fortis Probe Guide, pag. 2 – LINEAR: L6-24-D:** FOV: 26 mm
- tehnologie peste 190 de cristale	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – L6-24-D, linear probe:** Number of elements: 192
- permite lucrul cu 3 frecvente diferite in transmisie pentru modul B	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – L6-24-D, linear probe:** B-Mode frequency: 12.0, 16.0, 21.0 MHz
- permite lucrul cu 3 frecvente diferite in transmisie pentru modul Doppler Color	**Conform LOGIQ Fortis Spec Sheet, pag. 18 – L6-24-D, linear probe:** Color Doppler frequency: 9.2, 11.2, 12.2 MHz

1 buc sonda wireless, care constă dintr-o sondă cu două capete, care integrează atât sonda convexa, cât și liniar.	**Coform Vscan Air Product Data sheet pag 1** Vscan Air consists of a dual-headed probe
sonda convexa pentru aplicatii: abdomen, fetal/obstetrică, ginecologie, urologie, toracic/plămân, cardiac (adult și pediatric, 40 kg și mai mult), vascular/vascular periferice, musculo-scheletal (convențional), pediatrie, îndrumare intervențională (include plasarea acului/cateterului cu mâna liberă, lichid drenaj, blocaj nervos și biopsie)	**Coform Vscan Air Product Data sheet pag 2** Curved array transducer for deep scanning - Specific clinical applications and exam types include: abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung, cardiac (adult and pediatric, 40 kg and above), vascular/peripheral vascular, musculoskeletal (conventional), pediatrics, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy)
banda de frecvente de lucru acopera minimum intervalul: 2,2 -4,9 MHz cu centru frecventa de 3,3 MHz	**Coform Vscan Air Product Data sheet pag 2** Broad-bandwidth curved array: from 2 - 5 MHz with center frequency of 3.3 MHz
numar de elemente: minim 127	**Coform Vscan Air Product Data sheet pag 2** Number of elements: 128
adancimea de scanare: pina la 24 cm	**Coform Vscan Air Product Data sheet pag 2** Depth: up to 24 cm
sonda lineara pentru aplicatii: vascular/periferic vascular, musculo-scheletal (convențional și superficial), organe mici, toracice/plămâni, oftalmic, pediatrie, cefalic neonatal, intervențional ghidare (include plasarea acului/cateterului cu mâna liberă, drenaj lichid, blocaj nervos, acces vascular și biopsie)	**Coform Vscan Air Product Data sheet pag 2** Linear array transducer for shallow scanning- Specific clinical applications and exam types include: vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, ophthalmic, pediatrics, neonatal cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block, vascular access and biopsy)
banda de frecvente de lucru acopera minimum intervalul: 3,2 - 11 MHz MHz cu centru frecventa de 7,7 MHz	**Coform Vscan Air Product Data sheet pag 4** Broad-bandwidth linear array: from 3 - 12 MHz with center frequency of 7.7 MHz
numar de elemente: minim 190	**Coform Vscan Air Product Data sheet pag 4** Broad-bandwidth linear array: from 3 - 12 MHz with center frequency of 7.7 MHz
adancimea de scanare: pina la 8cm	**Coform Vscan Air Product Data sheet pag 4** Depth: up to 8 cm
ecran dimensiuni: de la 5 la 20 inch	**Coform Vscan Air Product Data sheet pag 4** Screen requirements, Size: from 5 to 20 inches
Memorie interna: 8GB	**Coform Vscan Air Product Data sheet pag 4** 8GB or more
B.3) PERIFERICE SI ALTE ACCESORII:	
Dispune de printer termic alb/negru integrat in ecograf	**Conform LOGIQ Fortis Datasheet, pag. 4** – Peripheral options: Integrated options for: Digital B&W thermal printer **Va fi inclus**

Dispune de posibilitate de upgradare cu printer termic color	**Conform LOGIQ Fortis Datasheet, pag. 4** – Peripheral options: Digital color thermal printer
Dispune de posibilitate de upgradare cu modul DVR	**Conform LOGIQ Fortis Datasheet, pag. 4 –** Peripheral options: Integrated options for: DVD video recorder
Dispune de posibilitate de upgradare cu pedala de control - 3 butoane	**Conform LOGIQ Fortis Datasheet, pag. 4 –** Peripheral options: Foot switch with programmable functionality
Dispune de posibilitate de upgradare cu adaptor pentru sonda TEE	**Conform LOGIQ Fortis Datasheet, pag. 14** – Probes: 6Tc-RS, trans-esophageal probe: TEE RS-DLP Adapter
Dispune de posibilitate de upgradare cu modul ECG	**Conform LOGIQ Fortis Datasheet, pag. 6** – Physiological input panel (Option): Physiological input: ECG, 1 channel
Dispune de posibilitate de upgradare cu cabluri ECG	**Conform LOGIQ Fortis Product Tree, pag. 15** – ECG Option: ECG cords IEC Style, ECG cords AHA styles
Dispune de posibilitate de upgradare cu modul wireless LAN	**Conform LOGIQ Fortis Product Tree, pag. 15** – Physiological input panel (Option): Wireless Option kit
Dispune de posibilitate de upgradare cu suport pentru sistemul de navigatie	**Conform LOGIQ Fortis Product Tree, pag. 16** – V Nav Hardware Options: Volume Navigation Stand
Dispune de posibilitate de upgradare cu kit pentru ac de urmarire virtuala V Nav	**Conform LOGIQ Fortis Product Tree, pag. 16** – VNAV Needle Tracking Options: Vnav eTRAX 16/18G Starter Kit
Dispune de posibilitate de upgradare cu suport pentru stocarea acului de urmarire atunci cand nu este folosit	**Conform LOGIQ Fortis Product Tree, pag. 16 –** VNAV Needle Tracking Options: Vnav eTRAX 18/20G Starter Kit
Dispune de posibilitate de upgradare cu kit pentru ac de urmarire activa	**Conform LOGIQ Fortis Product Tree, pag. 16** – VNAV Needle Tracking Options: Vnav eTRAX 12/14G Starter Kit
Dispune de posibilitate de upgradare cu senzor de urmarire virtuala	**Conform LOGIQ Fortis Product Tree, pag. 16** – VNAV Needle Tracking Options: Vnav eTRAX 14/16G Starter Kit
Dispune de posibilitate de upgradare cu senzori pentru navigatie volumetrica destinat sondelor	**Conform LOGIQ Fortis Product Tree, pag. 16** – VNAV Needle Tracking Options: V Nav Virtual Needle Tracker
Dispune de posibilitate de upgradare cu ac electromagnetic de urmarire activa pentru navigatia volumetrica	**Conform LOGIQ Fortis Product Tree, pag. 16** – VNAV Needle Tracking Options: V Nav Needle Tracking storage insert
C) CONFROMANTA DE SIGURANTA	

Echipamentul este clasificat conform **60601-1**, recunoscut si atestat de catre un laborator	**Conform LOGIQ Fortis Datasheet, pag. 15** – Safety conformance, The LOGIQ Fortis is: Certified to CSA CAN/CSA-C22.2 NO. 60601-1:14 General requirements for safety
Echipamenul respecta urmatoarele standarde de siguranta:	
IEC 60601-1	**Conform LOGIQ Fortis Datasheet, pag. 15** – Safety conformance, The LOGIQ Fortis is: CE Marked to EU Medical Device Regulation MDR 2017-745 and Council Directive 93/42/EEC on Medical Devices and conforms to the following standards for safety: IEC/EN 60601-1 Edition 3.1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	**Conform LOGIQ Fortis Datasheet, pag. 15** – Safety conformance, The LOGIQ Fortis is: CE Marked to EU Medical Device Regulation MDR 2017-745 and Council Directive 93/42/EEC on Medical Devices and conforms to the following standards for safety: IEC/EN 60601-1-2 Medial electrical equipment – Parts 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – requirements and tests
EN 60601-1-6	**Conform LOGIQ Fortis Datasheet, pag. 15** – Safety conformance, The LOGIQ Fortis is: CE Marked to EU Medical Device Regulation MDR 2017-745 and Council Directive 93/42/EEC on Medical Devices and conforms to the following standards for safety: IEC/EN 60601-1-6 Medical electrical equipment Parts 1 -6: General requirements for basic safety and essential performance – Collateral standard: usability
IEC 62366	**Conform LOGIQ Fortis Datasheet, pag. 15** – Safety conformance, The LOGIQ Fortis is: CE Marked to EU Medical Device Regulation MDR 2017-745 and Council Directive 93/42/EEC on Medical Devices and conforms to the following standards for safety: IEC/EN 62366 Application of usability engineering to medical devices
EN 62304	**Conform LOGIQ Fortis Datasheet, pag. 15 – Safety conformance, The LOGIQ Fortis is:** CE Marked to EU Medical Device Regulation MDR 2017-745 and Council Directive 93/42/EEC on Medical Devices and conforms to the following

	standards for safety: IEC/EN 62304 Software life cycle processes
IEC 60601-2-37	**Conform LOGIQ Fortis Datasheet, pag. 15 – Safety conformance, The LOGIQ Fortis is:** CE Marked to EU Medical Device Regulation MDR 2017-745 and Council Directive 93/42/EEC on Medical Devices and conforms to the following standards for safety: IEC/EN 60601-2-37 Medical electrical equipment – Parts 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
ISO 10993-1	**Conform LOGIQ Fortis Datasheet, pag. 15 – Safety conformance, The LOGIQ Fortis is:** CE Marked to EU Medical Device Regulation MDR 2017-745 and Council Directive 93/42/EEC on Medical Devices and conforms to the following standards for safety: ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing
C) GARANTIE SI CONDITII DE SERVICE:	
Garantie - 24 luni	DA din monetul instalari
Timp de răspuns la solicitare în perioada de garanție cel mult 48 ore la sediul beneficiarului / locația de instalare	DA
C.1) SERVICE POSTGARANTIE:	
Post-garantie: 8 ani	DA
Timp de răspuns la solicitare în perioada de garanție cel mult 48 ore la sediul beneficiarului / locația de instalare	DA
D) 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	DA
Instalare și punere în funcțiune de către personal autorizat si instruit de producator	DA
Instruire personal medical si tehnic la sediul beneficiarului în locația de instalare	DA
E) TERMEN DE LIVRARE:	
45 de zile de la primirea comenzii	DA/ pina la 15 octombrie 2022 conform solicitariilore

GE Healthcare

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC.

We

Manufacturer:
GE Vingmed Ultrasound AS
Strandpromenaden 45
3191 Horten, Norway

Declare under our sole responsibility that the device:

Vscan Air

Ultrasound imaging system application software
Software version**: 1.1**
Ref.: See Addendum.

GMDN Code : **40873**

Classification rule (93/42/EC 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.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical documentation, ref Technical File **DOC2506509**, 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 SÜD Product Service GmbH (Notified Body 0123), Certificate No.: G1 023782 0112, issued on September 02, 2019.
  - Harmonized standards applied on the product to which this declaration relates:

Standard	Description
EN 62366-1: 2015	Medical devices - Application of usability engineering to medical devices
EN 62304:2006 + A1:2015	Medical device software - Software life-cycle processes
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041:2008 + A1:2013	Information supplied by the manufacturer with medical devices

Wei Liwen, 17-Mar-2022
Regulatory Affairs Leader

Horten, Norway, 17 March 2022
Wei Liwen, Regulatory Affairs Leader

This EC declaration of conformity supersedes the previous declaration dated 12-March-2022 for the full production systems of Vscan Air

GE Healthcare

ADDENDUM TO THE DECLARATION OF CONFORMITY dated 17 March 2022

PRODUCT Name	GEHC Cat # [1]	Part number[2][5]	REF[3]
Vscan Air	N/A	GP000250	Vscan Air for iOS
	N/A	GP000240	Vscan Air for Android

OPTIONS AND ACCESSORIES [4]	GEHC Cat # [1]	Part number[2]	REF[3]
Vscan Air CL	H45611CB	GP000158	Vscan Air CL G1
	H45611AD	GP000153	Vscan Air CL C1
MyRemoteShare - 1 Years	H45611DG	N/A	N/A
MyRemoteShare - 3 Years	H45611DH	N/A	N/A
Vscan Air Fleet - 1 Year	H45611DJ	N/A	N/A
Vscan Air Fleet - 3 Years	H45611DK	N/A	N/A
Vscan Air Digital Solution - 1 Year	H45611DL	N/A	N/A
Vscan Air Digital Solution - 3 Year	H45611DM	N/A	N/A

Notes :

1. 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.
2. Part number identifies the device in the manufacturer's design, manufacturing and service documentation.
3. REF is affixed to the devices as product identifier under the harmonized symbol REF
4. Options and Accessories are compatible with the Vscan Air, and bear the CE-mark and, if applicable, Notified Body number corresponding to the EC Declaration under which it is CE-marked. GE Vingmed Ultrasound AS has verified the mutual compatibility of the device in combination with Vscan Air and included relevant information to users with the Vscan Air user manual. This activity was subject to appropriate methods of internal monitoring, verification and validation.
5. The Vscan Air part number GP000250, GP000240 will not be seen on the device

Wei Liwen 17-Mar-2022
Regulatory Affairs, Leader

Horten, Norway, 17March_2022 Wei Liwen, Regulatory Affairs Leader

This EC declaration of conformity supersedes the previous declaration dated 12-March -2022 for the full production systems of Vscan Air

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex II, and of the radio equipment directive 2014/53/EU, annex II, and of the RoHS directive 2011/65/EU

We

Manufacturer:	Manufacturing site:
GE Vingmed Ultrasound AS	**GE Healthcare Austria GmbH & Co OG**
Strandpromenaden 45	**Tiefenbach 15**
3191 Horten, Norway	**A-4871 Zipf, Austria**

Declare under our sole responsibility that the device:

Vscan Air CL

General ultrasound imaging system, battery-powered.

Software version: **1.1**

Ref.: See attached addendum.

GMDN Code: **60924**

Classification rule (93/42/EC 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 and Directive 2014/53/EU.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical documentation, ref Technical File DOC2506513, 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 SÜD Product Service GmbH (Notified Body 0123), Certificate No.: G1 023782 0112, issued on September 02, 2019.
  - Harmonized standards applied on the product to which this declaration relates:

Standard	Description
EN 60601-1:2006 + A1:2013	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-2-37:2008 + A1:2016	Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
EN 60601-1-2:2015	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN 60601-1-6:2010 + A1:2015	Medical electrical equipment, collateral standard
EN 62366-1: 2015	Medical devices - Application of usability engineering to medical devices
EN 62304:2006 + A1:2015	Medical device software - Software life-cycle processes
EN 1041:2008 + A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1789:2007+A2:2014	Medical vehicles and their equipment - Road ambulances
EN 13718-1:2014	Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
EN ISO 10993-1: 2018	Biological evaluation of medical devices
EN 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN60601-1-12:2015	General requirements for basic safety and essential performance medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Wei Liwen 17-Mar-2022

Regulatory Affairs Leader

Horten, Norway, 17March2022

Wei Liwen, Regulatory Affairs Leader

This EC declaration of conformity supersedes the previous declaration dated 3-August-2021 for the full production systems of Vscan Air CL

- For the directive 2011/65/EU (RoHS)
  - Technical documentation, ref Technical File DOC2506513, of the product to which this declaration relates.
- For the directive 2014/53/EU (Radio Equipment Directive)
  - Technical documentation, ref Technical File DOC2506513, of the product to which this declaration relates.
  - Harmonized standards applied on the product to which this declaration relates:

Standard	Description
EN 60601-1:2006 + A1:2013	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
ETSI EN 301 489-1 V2.2.1	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for Electro Magnetic Compatibility
ETSI EN 301 489-3 V2.1.1	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
ETSI EN 301 489-17 V3.2.4	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for Electro Magnetic Compatibility
ETSI EN300 328 V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
ETSI EN301 893 V2.1.1	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 300 330 V2.1.1	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 17 March 2022

PRODUCT Name	GEHC Cat # [1]	Part number[2]	REF[3]
Vscan Air CL	H45611CB	GP000158	Vscan Air CL G1
	H45611AD	GP000153	Vscan Air CL C1

OPTIONS AND ACCESSORIES [4]	GEHC Cat # [1]	Part number[2][5]	REF[3]
Vscan Air	N/A	GP000250	Vscan Air for iOS
	N/A	GP000240	Vscan Air for Android
International AC Adapters	H45611AH	GP200115 GP200114	N/A
Wireless Charger Pad	H45581ZZ/H45611CG	GP200303	N/A
Vscan Air Protective Carrying Case	H45611AG	GP200301	N/A

Notes :

1. 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.
2. Part number identifies the device in the manufacturer's design, manufacturing and service documentation.
3. REF is affixed to the devices as product identifier under the harmonized symbol REF
4. Options and Accessories are compatible with the Vscan Air CL, and bear the CE-mark and, if applicable, Notified Body number corresponding to the EC Declaration under which it is CE-marked. GE Vingmed Ultrasound AS has verified the mutual compatibility of the device in combination with Vscan Air CL and included relevant information to users with the Vscan Air user manual. This activity was subject to appropriate methods of internal monitoring, verification and validation.
5. The Vscan Air part number GP000250, GP000240 will not be seen on the device

Wei Liwen 17-Mar-2022
Regulatory Affairs Leader

Horten, Norway, 17March2022
Wei Liwen, Regulatory Affairs Leader

This EC declaration of conformity supersedes the previous declaration dated 3-August-2021 for the full production systems of Vscan Air CL

EC DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745
Following the directive 2011/65/EU, directive 2014/53/EU

We

Manufacturer and manufacturing site	EU Authorized Representative
GE Ultrasound Korea, Ltd.	**GE Medical Systems SCS**
9, Sunhwan-ro 214beon-gil,	283 rue de la Minière
Jungwon-gu, Seongnam-si	78530 BUC, France
Gyeonggi-do 13204, Republic of Korea	SRN: FR-AR-000000344
SRN: KR-MF-000001860	

Declare under our sole responsibility that the device:

LOGIQ Fortis

Basic UDI-DI: **8406821BUG00214GZ**

Identification number:

REF Catalog	H-Catalog Number	UDI-DI
LOGIQ Fortis HDU	**H43302LA**	**00195278405326**
LOGIQ Fortis LCD	**H43302LB**	**00195278405333**

Intended Purpose: The LOGIQ Fortis is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.

EMDN Code: **Z110401**
EMDN Description: Ultrasound Scanners

GMDN Code: **40761**
GMDN Description: General-purpose ultrasound imaging system

UMDNS Code: **15-976**

Classification: **IIa**
Classification rule (Annex VIII): **Rule 10, Class: IIa**

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that 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 (RoHS) and the directive 2014/53/EU on the radio equipment (RED).

This conformity is based on the following elements:

- Technical Documentation reference: DOC2379389, of the product to which this declaration relates.
- EC certificate No. HZ 2004702-01:
  - Conformity assessment procedure followed: Annex IX of the medical device regulation 2017/745
  - Delivered by TUV Rheinland LGA Products GmbH (Notified Body n° 0197)

This EC declaration of conformity is the initial release.

SIGNATURE:

Date of issue:	13-12-2021
Place of issue:	China
Name:	Qingmeng Chen
Function:	Regulatory Affairs Program Manager
Signature:	

Qingmeng Chen

ADDENDUM TO THE EC DECLARATION OF CONFORMITY
LOGIQ Fortis including accessories and components
dated 13-12-2021

Product Description	H-Catalog Number[1]
Ultrasound Console	
LOGIQ Fortis HDU Console	H43302LA / 6602000
LOGIQ Fortis LCD Console	H43302LB / 6601000
Probe Options[2]	
IC5-9-D	H40442LK
ML6-15-D	H40452LG
L8-18i-D	H40452LL
C2-9-D (XDClear)	H40462LN
C1-6-D (XDClear)	H40472LT
C1-6VN-D (XDClear)	H40472LW
C2-9VN-D (XDClear)	H40472LY
C3-10-D (XDClear)	H40482LB
M5Sc-D (XDClear)	H44901AE
L2-9-D	H44901AI
L2-9VN-D	H44901AJ
6Tc-RS	H45551ZE
C2-7-D	H46422LM
C2-7VN-D	H46422LN
P2D	H4830JE
RIC5-9-D	H48651MS
RAB6-D	H48681MG
P6D	H4830JG
BE9CS-D	H40482LE
L3-12-D	H48062AA
6S-D	H45021RR
L6-24-D Probe	H4920HF
TEE Probe Accessories[2]	
TEE RS-DLP Adapter	H46352LK
Adult TEE Clip-on Bite Guard	H45511EE
Adult TEE Clip-on Bite Guard Opr.	H45521CB
Adult TEE Scanhead Protection Cover	H45521CK
Adult TEE Conventional Bite Guard	H45521JH
BITE HOLE INDICATOR	H45531HS
TEE STORAGE RACK	H45551NM
Software Options	
Advanced Security	H46622LL
Coded Contrast	H43332LA
Parametric Imaging	H43332LB
Cardiac AFI	H46622LN
LOGIQ Exx DVR	H4918DR
Report Writer	H46622LR
Stress Echo	H46622LS
Tricefy	H46622LT
LOGIQ Apps	H46622LW
KOIOS SW	H46622LY
LOGIQ Exx KOIOS Thyroid	H4920KT
LOGIQ E10 KOIOS INSTALL	H4919KI

Product Description	H-Catalog Number[1]
KOIOS 3.x INSTALL	H4921KY
Scan Assistant	H46622LZ
Advanced Probes	H46612LS
AUTO IMT	H46612LT
B Steer+	H46612LW
B-FLOW	H46612LY
Compare Assistant	H46612LZ
DICOM	H46622LA
FLOW QA	H46622LB
Measure Assist Breast	H46622LC
Measure Assist OB	H46622LD
Elastography	H43332LC
Elasto QA	H43332LD
Shear Wave Elastgraphy	H46622LE
LOGIQ Exx SRI HD Type2	H4920SR
UGAP	H46622LH
SonoNT SonoIT	H46622LJ
LOGIQ Exx VNAV Image	H4920VR
Hepatic Assistant - SWE-UGAP	H43332LE
Omni View	H43332LF
STIC	H43332LG
TUI	H43332LH
VCI-Static	H43332LJ
VOCAL_II	H43332LK
Thyroid Productivity	H43332LL
Breast Productivity	H43332LM
Vita on Demand	H43332LN
Hardware Options[2]	
CW Doppler	H43342LA
Realtime 4D	H43342LB
ECG Option	H43342LC
Scan on battery option kit	H43342LD
Power Assistant	H43342LE
Volume Navigation	H43342LF
Volume Navigation for V-Nav Inside T1	H43372LK
Wireless Option	H43342LG
S-Video Option	H43342LH
Pencil CW	H43342LJ
Peripheral Options[2]	
USB FOOTSWITCH 3 BUTTON	H46732LF
SONY UPD25MD COLOR PRINTR	H4911JT
BW Printer Installation Kit T1	H43342LK
LOGIQ Exx Protective Cover	H4918DC
LOGIQ Exx Inkjet Printer	H4918RP
LOGIQ Fortis High Cabinet	H43342LL
LOGIQ Fortis Low Cabinet	H43342LM
LOGIQ Fortis Side Cabinet	H43342LN
5inch bay Option	H43342LP
An Keyboard Assembly	
AN Keyboard ENGLISH	H43342LR
AN Keyboard GERMAN	H43342LS
AN Keyboard FRENCH	H43342LT
AN Keyboard GREEK	H43342LW
AN keyboard NORWEGIAN	H43342LY

Product Description	H-Catalog Number[1]
AN Keyboard SWEDISH	H43352LA
Accessories[2]	
Ethernet protection Cable	H43272LJ
FC389,ECG CABLE SET	H45521AL
VNav Stand (Offboard)	H4908NS
ECG CABLE - AHA STYLE	H4910EC
VNav NEEDLE TRACKING	H4910NT
VNav VirtuTRAX Starter Kit	H4910NY
ECG Cables IEC Style	H4911JC
VNav Virtual Tracker	H4911NG
VNav Active Tracker kit	H4913AT
VNav Needle Tracking storage insert	H4913NS
VNav Needle Tracking Kit - 18/20g or less	H4913NT
VNav ETRAX 12 14G ST KT	H4913NU
VNav ETRAX 14 16G ST KT	H4913NV
VNav Probe sensors	H4913PS
VNav MR Active Tracker	H4915MT
Small Probe Holder	H43352LC
VERTICAL TV PROBE HOLDER	H43352LD
TVTR Probe Holder	H43352LE
PROBE CABLE HANGER	H44412LA
OPTION TRAY BOX	H43372LF
OPTION TRAY Bracket	H43372LG
Power Cords Destination Sets	
Power Cord 220V for EU	H46342LZ
Power Cord DK STD C13 GRY	H46692LK
DESTINATION SET UK	H46712LM
DESTINATION SET SWISS	H46712LS
DESTINATION SET DENMARK	H46712LT
DESTINATION SET ITALY	H46722LD
V-nav Options[2]	
ML6-15 M_BPSY_TRU3D_SKIT	H40432LK
C3-10 VNav Holder Starter Kit	H40482LF
IC5-9 V NAV BRACKET	H4908NF
L8-18I V NAV BRACKET	H4908NH
M5S V NAV BRACKET	H4908NM
Biopsy Kits[2]	
E721 STARTER KIT	E8385MJ
IC5-9-D Reusable Biopsy Guide	H40412LN
ML6-15 M_BIOPSY_SKIT	H40432LJ
C2-7 Biopsy Kit	H40482LK
C2-7 Biopsy Kit Stainless	H40482LL
L2-9 Needle Guide Starter Kit	H44901AM
M5Sc-D Biopsy Bracket	H45561FC
RAB BIOPSY STARTER KIT	H46701AE
RIC5-9-D Biopsy Guide	H46721R
C2-9 Biopsy Starter Kit	H4913BA
C1-6-D Verza Biopsy Starter Kit	H4917VB
C1-6-D Biopsy Starter Kit	H4913BB
L3-12-D Biopsy Kit	H48302AA
RAB6-D BIOPSY STARTER KIT	H48681ML
BE9CS Biopsy Kit 742-401	H42742LJ

Notes:

[1] *H-Catalog number identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sales contract, order processing documents and shipping documents.*

[2] *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 Ultrasound Korea Ltd. has verified the mutual compatibility of the devices in combination with LOGIQ Fortis and included relevant information to users with the LOGIQ Fortis instructions for use.*

End of Document

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 7697 rev. 18**
Délivrée à Paris le 14 septembre 2020
Issued in Paris on September 14th, 2020

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu,
SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositif ou système de diagnostic par ultrasons

Ultrasound diagnostic device or system

Voir document complémentaire GMED / See GMED additional document
n° 36988

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P183396, P601203, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P183396, P601203, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **September 14th, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED SAS GMED GROUPE LNE

Lionel DREUX
Certification Director

GMED_b2p3_new2020-V0-04-

GMED - 7697 rev. 18
Modifie le certificat 7697-17

Ce document complémentaire GMED n° 36988 rev. 0 atteste de la validité du certificat CE n° 7697 rev. 18 au regard des informations listées ci-dessous.

This GMED additional document N° 36988 rev. 0 attests to the validity of CE certificate n ° 7697 rev. 18 with regard to the information listed below.

Fabricant / *Manufacturer*:

GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu,
SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P7**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P9**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P10**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S6**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S8t**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S10**	**IIa**

Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S10 Expert**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON P6**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON P8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON SWIFT**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON SWIFT+**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 Expert**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 Pro**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 XDclear2.0**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ E10s**	**IIa**

Site couvert et Activités / *Locations and Activities*

Site / *Location*	Activités / *Activities*
GE ULTRASOUND KOREA, Ltd. **9, Sunhwan-ro 214beon-gil, Jungwon-gu,** **Seongnam-si, Gyeonggi-do, REPUBLIC OF KOREA** **équivalent à** *equivalent to* **GE ULTRASOUND KOREA, Ltd.** **65-1, Sangdaewon-dong, Jungwon-gu,** **Seongnam-si, Gyeonggi-do - 462-120 REPUBLIC OF KOREA**	**Conception, fabrication et contrôle final** *Design, manufacture and final control*

Lionel DREUX
Certification Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme notifié n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr 720 GMED 0901-4 rev 0 du 31/08/2020

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 075707 0058 Rev. 02

Holder of Certificate: **GE Healthcare Austria GmbH & Co OG**
Tiefenbach 15
4871 Zipf
AUSTRIA

Facility(ies):
GE Healthcare Austria GmbH & Co OG
Tiefenbach 15, 4871 Zipf, AUSTRIA

Design and Development, Production and Distribution of Diagnostic Ultrasound Systems, Probes and Standalone Software for Ultrasound-Image Processing

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Diagnostic Ultrasound Systems, Probes and Standalone Software for Ultrasound-Image Processing**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 075707 0058 Rev. 02

Report No.: 713202497

Valid from: 2021-11-20
Valid until: 2024-04-23

Date, 2021-11-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Lloyd's Register

Current issue date: 28 September 2020
Expiry date: 27 September 2023
Certificate identity number: 10293605

Original approval(s):
ISO 14001 - 28 September 2017

Certificate of Approval

This is to certify that the Management System of:

GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

ISO 14001:2015

Approval number(s): ISO 14001 – 0043295

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.

Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Location	Activities
GE Medical Systems SCS 283 rue de la Minière, 78530 BUC, France	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
GEMS SCS 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Austria GmbH & Co OG Technologiestr. 10, 1220 WIEN, Austria	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare BVBA Kouterveldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Bulgaria LTD Dragan Tzankov Blvd. 36, World Trade Centre, 1040 SOFIA, Bulgaria	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Česká republika, s.r.o. Bucharova 2641/14, Explora Business Centre, Jupiter Building, 158 00 PRAHA 5, Czech Republic	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Location	Activities
GE Healthcare Danmark A/S Park Allé 295, 2605 BRONDBY, Denmark	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Finland Oy Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Information Technologies GmbH Munzingerstr. 3a-5, 79111 FREIBURG, Germany	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
GE Healthcare GmbH Beethovenstr. 239, 42655 SOLINGEN, Germany	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare S.A. 8-10 Sorou, Maroussi, 151 25 ATHENS, Greece	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Magyarország Kft. Bence utca 3., 1138 BUDAPEST, Hungary	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Location	Activities
GE Medical Systems Ireland Ltd Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Italia SpA Via Galeno 36, 20126 MILAN, Italy	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric Kazakhstan LLP 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Nederland BV De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Norge AS Vitaminveien 1A, 0485 OSLO, Norway	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Polska Sp.z o.o. ul. Wołoska 9, 02-583 WARSAW, Poland	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Location	Activities
General Electric Healthcare Portugal, Sociedade Unipessoal, Lda. Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems SRL. 301-311 Barbu Vacarescu St., District 2, Lakeview Building, 3rd floor, 020276 BUCHAREST, Romania	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare LLC 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Holdings d.o.o. Bulevar Mihaila Pupina 6/17 PC,, Usce, Novi Beograd, BELGRADE, 11070, Republic of Serbia	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric International (Slovensko), s.r.o. Prievozská 4, 821 09 BRATISLAVA, Slovakia	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric Healthcare España, S.A.U Calle Gobelas 35-37, Urbanizacion La Florida, 28023 MADRID, Spain	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

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Certificate identity number: 10293605

Certificate Schedule

Location	Activities
GE Healthcare Sverige AB Vendevägen 89, 182 32 DANDERYD, Sweden	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Schweiz AG Europastrasse 31, 8152 GLATTBRUGG, Switzerland	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	**ISO 14001:2015** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

UKAS MANAGEMENT SYSTEMS
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Current issue date: 21 September 2020
Expiry date: 27 September 2023
Certificate identity number: 10293595

Original approval(s):
ISO 45001 - 28 September 2017

Certificate of Approval

This is to certify that the Management System of:

GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

ISO 45001:2018

Approval number(s): ISO 45001 – 00027009

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
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Certificate Schedule

Location	Activities
GE Medical Systems SCS 283 rue de la Minière, 78530 BUC, France	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GEMS SCS 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare BVBA Koutervеldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Bulgaria LTD Dragan Tzankov Blvd. 36, World Trade Centre, 1040 SOFIA, Bulgaria	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Česká republika, s.r.o. Bucharova 2641/14, Explora Business Centre, Jupiter Building, 158 00 PRAHA 5, Czech Republic	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Finland Oy Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

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Certificate Schedule

Location	Activities
GE Medical Systems Information Technologies GmbH Munzingerstr. 3a-5, 79111 FREIBURG, Germany	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare GmbH Beethovenstr. 239, 42655 SOLINGEN, Germany	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare S.A. 8-10 Sorou, Maroussi, 151 25 ATHENS, Greece	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Magyarország Kft. Bence utca 3., 1138 BUDAPEST, Hungary	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Ireland Ltd Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Italia SpA Via Galeno 36, 20126 MILAN, Italy	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

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Certificate Schedule

Location	Activities
GE Medical Systems Polska Sp.z o.o. ul. Wołoska 9, 02-583 WARSAW, Poland	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management. repair and installation of medical devices
General Electric Healthcare Portugal, Sociedade Unipessoal, Lda. Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems SRL. 301-311 Barbu Vacarescu St., District 2, Lakeview Building, 3rd floor, 020276 BUCHAREST, Romania	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare LLC 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Holdings d.o.o. Bulevar Mihaila Pupina 6/17 PC,, Usce, Novi Beograd, BELGRADE, 11070, Republic of Serbia	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management. associated with sales, marketing, services, repair and installation of medical devices

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Certificate Schedule

Location	Activities
General Electric International (Slovensko), s.r.o. Prievozská 4, 821 09 BRATISLAVA, Slovakia	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric Healthcare España, S.A.U Calle Gobelas 35-37, Urbanizacion La Florida, 28023 MADRID, Spain	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Sverige AB Vendevägen 89, 182 32 DANDERYD, Sweden	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Schweiz AG Europastrasse 31, 8152 GLATTBRUGG, Switzerland	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Nederland BV De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

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Certificate identity number: 10293595

Certificate Schedule

Location	Activities
GE Healthcare Austria GmbH & Co OG Technologiestr. 10, 1220 WIEN, Austria	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric Kazakhstan LLP 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	**ISO 45001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

UKAS MANAGEMENT SYSTEMS
001

Current issue date: 21 September 2020
Expiry date: 27 September 2023
Certificate identity number: 10293599

Original approval(s):
ISO 50001 - 25 January 2018

Certificate of Approval

This is to certify that the Management System of:

GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

ISO 50001:2018

Approval number(s): ISO 50001 – 0043293

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
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Certificate identity number: 10293599

Certificate Schedule

Location	Activities
GE Medical Systems SCS 283 rue de la Minière, 78530 BUC, France	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
GEMS SCS 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare BVBA Koutervelstraat 20, Eagle Building, 1831 DIEGEM, Belgium	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Finland Oy Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Information Technologies GmbH Munzingerstr. 3a-5, 79111 FREIBURG, Germany	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
GE Healthcare GmbH Beethovenstr. 239, 42655 SOLINGEN, Germany	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

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Lloyd's Register

Certificate identity number: 10293599

Certificate Schedule

Location	Activities
GE Medical Systems Ireland Ltd Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Italia SpA Via Galeno 36, 20126 MILAN, Italy	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric Healthcare Portugal, Sociedade Unipessoal, Lda. Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare LLC 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric Healthcare España, S.A.U Calle Gobelas 35-37, Urbanizacion La Florida, 28023 MADRID, Spain	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Sverige AB Vendevägen 89, 182 32 DANDERYD, Sweden	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

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Certificate identity number: 10293599

Certificate Schedule

Location	Activities
GE Medical Systems Schweiz AG Europastrasse 31, 8152 GLATTBRUGG, Switzerland	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Medical Systems Nederland BV De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
General Electric Kazakhstan LLP 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
GE Healthcare Austria GmbH & Co OG Technologiestr. 10, 1220 WIEN, Austria	**ISO 50001:2018** Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.

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*Das Gerät ist für den eingeschränkten Einsatz außerhalb professioneller medizinischer Einrichtungen geprüft. Die Verwendung ist auf die im Benutzerhandbuch beschriebenen Umgebungseigenschaften beschränkt. Bitte wenden Sie sich an Ihren GE Healthcare-Vertriebsmitarbeiter, um detaillierte Informationen zu erhalten.

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Dicom Server **Shared Folder** **Andere Apps**

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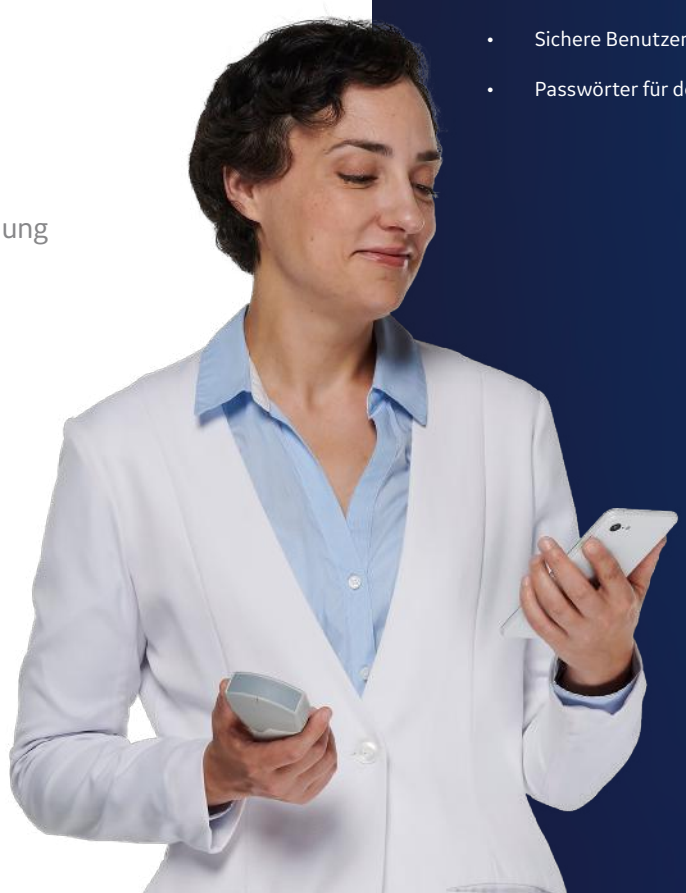
- Sichere Benutzerauthentifizierung
- Passwörter für den Zugriff auf Patientendaten erforderlich



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Signalverarbeitung in Konsolenqualität
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