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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 3 octobre 2013  Verslag van de vergadering van 3 oktober 2013 |

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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Liste de présence – Aanwezigheidslijst | | | | | | | Membres Effectifs  Effectieve leden | P / A = Présent / Aanwezig  E / V = Excusé / Verontschuldigd | **Membres suppléants**  **Plaatsvervangende leden** | | P / A = Présent /  Aanwezig  E / V = Excusé / Verontschuldigd | | | Els Tuyls |  | Marianne Van Malderen | | E/V | | | Awatif Jebari | E/V | Emmanuelle Gay | | P/A | | | Maries Merken |  | Rita Cornélis | |  | | | Guibert Crèvecoeur |  | Jean-Claude Mignolet | |  | | | Isabelle De Pau ad it. Tom Clarijs | P/A | Annie Vanderlinck | |  | | | Guido Van Nooten | P / A | Yves Taeymans | |  | | | Hein Heidbüchel |  | Rik Willems | |  | | | Kristel De Vogelare |  | Daniel Mojet | |  | | | Claude Hanet |  | André Waleff | |  | | | Véronique Kepenne |  | Johan Somville | |  | | | Florence Lefranc |  | Gaetane Stassijns | |  | | | Ludo Willems |  | Dominique Toye | |  | | | Annick Verbiest |  | Philippe Noirhomme | |  | | | Jacques Destiné |  | J-L Vanoverschelde | |  | | | Olivier Debeir |  | Marie-José Tassignon | |  | | | Wim Verlinden |  | Thierry Descamps | |  | | | Dominique Wouters |  | Tinne Leysen | |  | | | Christine Barzin |  | Jan Saevels | | P/A | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps |  | Fien Aerts | |  | | |  |  | Carole Absil | |  | | | Bart Mersseman | P/A | Marine Debaut | | P / A | | | Représentants de l’AFMPS - Vertegenwoordigers van het FAGG | | | | | | | Vanackere Sébastien | Lambot Damien | | Dejehansart Aline | |  | | Julie Roothooft | Sibylle Watteeuw | | Badisco Liesbeth | |  | | Schuyvinck Anne | Jauniaux Alexandre | |  | |  | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

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Le président ouvre la réunion à 13h15. Le quorum n’est pas atteint.

*De voorzitter opent de vergadering om 13u15. Het quorum werd niet bereikt.*

1. **Ordre du jour  / *Dagorde***

Approuvé avec le rajout de 2 points varia :

*Goedgekeurd met toevoeging van twee variapunten betreffende:*

* 14021 : Terumo - COBE® Spectra Bone Marrow Processing Set
* 12723 : Terumo - TerumoR Advanced Perfusion System 1

1. **PV de la réunion précédente /*Verslag van de vorige vergadering***

Approuvé / *Goedgekeurd*

1. **Conflits d’intérêt / *Belangenconflicten***

nihil

1. **Suivi des incidents/ *Opvolging van de incidenten***

Nihil

1. **Incidents**

Pas de dossier présenté oralement durant cette réunion./ *Geen dossiers die mondeling werden gepresenteerd*   
198 FSCA soumis à la Commission / 198 FSCAs werden voorgelegd aan de commissie:

* MitraXs Atrial Retractor from (*see fsn 9263*)
* Mikro 120
* Kern ; MHS300K100M
* Baxter Colleague Triple Channel Volumetric Infusion Pumps; Baxter Healthcare Corporation, Medication Delivery Division, Deerfield, IL 60015 U.S.A., Made in Singapore
* Mini Crosser M1 (*see fsn 10729*)
* Vector TAS Modular Driver
* SERVO-i and SERVO-s Ventilator Systems
* Olympus OES-Pro Working elements (WA22066A, WA22067A) Olympus SurgMaster working elements (WA22366A, WA22367A)
* C-Series Clinac or Trilogy
* LOGIQ E9 ULTRASON
* AXIOM Iconos MD & R100
* XVI
* T2 Ankle Arthrodesis Nail
* S5 Perfusion System, C5 Perfusion System
* NicVue Software/NicVue
* Wingspan Stent System and Gateway PTA Balloon Catheter
* syngo RT Therapist
* VLM VESDA Device / Gradient Supervision - Aera/Skyra
* syngo Imaging XS
* Bravo pH Monitoring devices
* da Vinci S Surgical System, da Vinci Si Surgical System, and da Vinci Sie Surgical System
* Millennium or Mark MLC
* CARTO 3 SYSTEM AND CARTO ?3 RMT SYSTEM
* IMPAX Cardiovascular (CV)
* MultiDiagnost Eleva FD
* DALI 500 Kit (REF 9798201), DALI 750 Kit (REF 9798211), DALI 1000 Kit (REF 9798221), DALI 1250 Kit (REF 9798241)
* Portal Vision
* 4D Integrated Treatment Console (4DITC) and TrueBeam
* INFINIA
* MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, D80, MX600, MX700, MX800/ IntelliVue
* Brilliance CT Big Bore, EBW, GEMINI GXL 16, GEMINI TF 16, GEMINI TF 64, and GEMINI TF Big Bore
* Eclipse Treatment Planning System
* ARIA Radiation Oncology System
* Brilliance Workspace Portal (*see fsn 11146*)
* HeartStart FR3
* Sarns Soft-Flow Aortic Cannula with angled tip (*see fsn 11150*)
* All versions of BrainSCAN and iPian RT Dose and iPian RT treatment planning software.
* ACUSON & SONOLINE Antares
* LINAC / MHI-TM2000 linear Accelerator System/ VERO LINAC System/ MHI (*see fsn* *11228*)
* Brilliance 64 and Ingenuity CT (*see fsn 11258*)
* SUPERA VERITAS Self-expanding Nitinol Stent Peripheral Vascular & Billary System
* MultiDiagnost Eleva FD
* QuickSite and QuickFlex Left Ventricular CRT Leads (*see fsn 11273*)
* MOSAIQ 2.00X3 SP5, safety update and maintenance of IB
* UV HomeChoice Automated PD Set with Cassette 4-Prong, HomeChoice Automated PD Set woth Cassette 4-Prong and 8-Prong, 5-Prong Manifold Set with System II Connectors
* Fluido Junior Disposable Set, Fluido Junio warning unit
* ModuLeaf / MMLC Safety Bar & Trolley Label
* FLOSEAL Hemostatic Matrix (*see fsn 11293*)
* BRIO Implantable Pulse Generator
* DIC / ARIA Standard (*see fsn 11311*)
* DigitalDiagnost (*see fsn 11322*)
* End Attachment Low (for Bed Rail REKO 151040, 151050)
* Portal Vision
* Atlas PTA Balloon Dilatation Catheter (*see fsn 11350*)
* MLCi and MLCi2 (see fsn 11355)
* Kryptonite Bone Cement / Kryptonite-X Radiopaque Bone Cement (Kryptonite) (*see fsn* *11368*)
* DePuy Cemented, Polished and Cobalt Chromium Alloy Hip Stems in combination with metal-on-metal (MoM) articulations
* syngo.plaza, Update Package VA20C NAS Archives
* MultiLoc Proximal Humeral Nail 8.0mm, right
* MOSAIQ
* Practix33plus
* XiO
* XVI (*see fsn 11408*)
* Universal ECG 12 Lead IEC ECG Device (*see fsn 11410*)
* MIRS, Synthes Minimally Invasive Reduction Screw System (*see fsn 11421*)
* syngo.plaza
* TrueBeam and TrueBeam STx
* Practix Convenio (*see fsn 11473*)
* ACUSON S2000 (*see fsn 11480*)
* DeltaMotion Cup
* Systeme d'inflation FLAMINGO / FLAMINGO Inflation device
* Carpentier-Edwards Porcine Valve (Surgical), SAV Porcine Valve (Surgical), Carpentier-Edwards PERIMOUNT Valve (Surgical), Carpentier-Edwards PERIMOUNT Magna (Surgical), Carpentier-Edwards PERIMOUNT Magna Ease (Surgical), Carpentier-Edwards PERIMOUNT Magna Mitral (Surgical), Carpentier-Edwards PERIMOUNT Magna Mitral Ease (Surgical), Edwards Sapien XT Transcatheter Heart Valve, Ascendra 2 Kit (for Transcatheter Valves), NovaFlex+ Kit (for Transcatheter Valves), NovaFlex Kit (for Transcatheter Valves)
* Brilliance iCT and iCT SP (*see fsn 11511*)
* Monoject Insulin Safety Syringe
* TrueBeam and TrueBeam STx (*see fsn 11572*)
* Brilliance iCT and iCT SP (see fsn 11575)
* Sarns High-flow Aortic Arch Cannula - Sarns Flexible Arterial Cannula (*see fsn 11602*)
* Syramed SP6000 + Volumed VP7000
* Sarns Antegrade Cardioplegia Cannula (*see fsn 11611*)
* Other-Sonic Generic Ultrasound Transmission Gel
* IntelliSpace Portal v4.0 and v4.0.1 and EBW (CT) 4.5.0, 4.5.2, 4.5.3, 4.5.4 (*see fsn* *11641*)
* MultiDiagnost Eleva FD and II (*see fsn 11659*)
* ConchaTherm Neptune Heated Humidifier
* Alumina Femoral Ceramic Head - V40 Taper +O.Omm (*see fsn 11707*)
* syngo RT Therapist / ARTISTE
* Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers)
* Focal RFC 35256
* Monaco RFC 35238
* HeartStart MRx Defibrillator Monitor
* V-SignTM Sensor 2 / SDMS (SenTec Digital Monitoring System) (see fsn 11768)
* NIDEK Medical MARK5 NUVO 8 STD, 115 V~60Hz - 500W, NIDEK Medical MARK5 NUVO 8 /OCSI, 230 V~50/60Hz - 420 W., NIDEK Medical NUVO LITE MODEL 525 OCSI, 115V -60Hz - 330W, NIDEK Medical NUVO LITE MODEL 520 STD, 115V - 60Hz - 330W, NIDEK Medical NUVO LITE MODEL 925 OCSI, 230V - 50Hz - 300W, NIDEK Medical MARK5 NUVO / M5C5, 115 V ~60Hz - 410 W, NIDEK Medical M5C5/ MARK5 NUVO/STD, 230 V~50/60 Hz - 420 W, NIDEK Medical NUVO LITE MODEL 925 OCSI, 3LPM 230V - 60Hz - 280W, NIDEK Medical M5C5/ MARK5 NUVO/OCSI, 230 V~50/60 Hz -420 W.
* AW Server (*see fsn 11787*)
* HeartStart MRx Defibrillator Monitor (*see fsn 11789*)
* pendiq, SmartPlus (*see fsn 11815*)
* DIC and ARIA Standard
* OCT Viewer - 3D optical coherence tomography 3D OCT-1000/3D OCT-1000 MARKII\*- 3D OC -2000/3D OCT-2000 (FA plus)MARKII,(FA plus) (*see fsn 11818*)
* Precise Digital Accelerator, Synergy Platform, Synergy (*see fsn 11830*)
* Carescape B650 (*see fsn 11842*)
* HemoDraw Closed Blood Sampling System
* PROXIMATE HCS Procedure for Prolapse and Hemorrhoids (PPH) Set, PROXIMATE PPH Procedure for Prolapse and Hemorrhoids Set
* Impax Cardiovascular (CV) (*see fsn 11893*)
* Exceed ABT (*see fsn 11894*)
* Optima XR220amx / Optima XR200amx / Brivo XR285amx (*see fsn 11913*)
* HALO FLEX Energy Generator
* Surican port cannula G20/25 mm 90 Deg (*see fsn 11928*)
* Eclipse Treatment Planning System
* SL75/5 (*see fsn 11936*)
* Brilliance 64 and Ingenuity CT (*see fsn 11938*)
* Armada 35 and Armada 35 LL PTA Catheter (*see fsn 11950*)
* Multidiagnost Eleva FD (*see fsn 11954*)
* syngo Imaging XS (*see fsn 11994*)
* syngo.plaza (*see fsn 11996*)
* vascular catheters: Embolectomy, Biliary and Irrigation Catheters (*see fsn 12001*)
* Terumo Advanced Perfusion System 1
* INADINE Povidone Iodine Non-Adherent Dressing
* Thyroid Uptake and Well Counter System (*see fsn 12015*)
* 6.5 Cancellous Bone Screw 25mm and 35mm (*see fsn 12018*)
* SureSigns VS Series Monitor (*see fsn 12022*)
* ACTIFUSE ABX, Actifuse MIS (*see fsn 12027*)
* Surican port cannula G20/25 mm 90 Deg & Surican port cannula G20/15 mm 90 Deg (*see fsn 12033*)
* Clinac, Trilogy, Novalis Tx and Unique accelerators (*see fsn 12064*)
* MIRS Polyaxial Screw Body, MIRS Locking Cap, one-step
* MOSAIQ
* Fluoroscan Mini C-arm
* Battery for XL Defibrillator/Monitor HeartStart (*see fsn 12093*)
* Heated Ventilator Circuit / Armstrong Medical (*see fsn 120107*)
* ILLICO Ti Cannulated Polyaxial Screws (*see fsn 12114*)
* BD Venflon Obturator (*see fsn 12119*)
* Products packaged at Wright Medical Toulon Facility (*see fsn 12143*)
* Dash 3000, 4000, 5000 (*see fsn 12148*)
* Hemodialysis Machine
* Terumo Tubing Sets (*see fsn 12171*)
* Discovery NM 630 & Discovery NM/CT 670 (*see fsn 12209*)
* Centricity PACS
* TriVascular Fill Polymer Kit (*see fsn 12215*)
* FCR G02 (*see fsn 12246*)
* Giraffe and Panda Warmer T-Piece Resuscitation System with blender field upgrade installed
* TM Ardis Interbody System Inserter (*see fsn 12272*)
* ExoSeal Vascular Closure Device (VCD)
* Micro dissection needle electrode 105 x 0,3 mm
* Carescape B20 Patient Monitor, Carescape B 40 Patient Monitor (*see fsn 12289*)
* Pflegebett Amara; Pflegebett Amara-Tero (*see fsn 12307*)
* Click'X Pedicle Screw 5.2mm, L 40mm / Trochanteric Nail Kit
* cardiolife TEC-5500K series
* Extended Brilliance Workspace (EBW) (*see fsn 12326*)
* MCA Attachments and Cutting Burrs / MICRO CURVED ATTACHMENT (*see fsn* *12354*)
* Carestream DRX-1 System (*see fsn 12363*)
* Zimmer Versys and Slotted Provisional Femoral Heads
* MEDRAD AVANTA HAND CONTROLLER SHEATH (*see fsn 12393*)
* Sonoline G40 , Acuson X150 (*see fsn 12418*)
* ENSEAL G2 Curved and Straight Tissue Sealer (*see fsn 12422*)
* Corpuls 3
* Philips IntelliVue Information Center/Client and Philips IntelliVue Information Center iX
* Pipeline Embolization Device (PED)
* STERRAD NX Cassette (*see fsn 12469*)
* ECMO Heater (*see fsn 12472*)
* Accent SR and Accent DR
* DualHemo MCable of the Infinity Acute Care System (*see fsn 12490*)
* SureSigns VS Series Monitor (*see fsn 12701*)
* Brilliance 64 and Ingenuity CT
* Thopaz Docking Station (battery charger) (*see fsn 12809*)
* Guardian II and Guardian II NC Hemostasis Valve with Guidewire Introducer
* REIN. MAGILL / Reinforced Endotracheal Tube Murphy, Magill, Murphy with stylet and Magill with stylet (*see fsn 12891*)
* Archer Super Stiff Guidewire
* Archer Super Stiff Guidewire
* CyberKnife Robotic Radiosurgery System. Subsystem: Iris Variable Aperture Collimator option
* FLAMINGO Inflation device
* Wallace Sure-Pro Embryo Replacement Catheter, Wallace Sure-Pro Ultra Embryo Replacement Catheter (*see fsn 12959*)
* Universal Set (*see fsn 12968*)
* Ojemann Cortical Stimulator (*see fsn 13046*)
* User Manuals for the da Vinci S Surgical System (Model IS2000), da Vinci Si Surgical System (Model IS3000) and da Vinci Si-e Surgical System (Model IS3000) (*see fsn* *13085*)
* MatrixMANDIBLE Screws in Clips, MatrixNeuro Screws in Clips

MatrixMIDFACE Screws in Clips & MatrixORTHOGNATICS Screws in Clips (*see fsn* *13103*)

* Zilver PTX Drug-Eluting Peripheral Stent
* Wire Tightener (*see fsn 13108*)
* Device for nail fixation / Compression device *(see fsn 13117*)
* Biosure Driver, Biosure Ratchet Driver (*see fsn 13120*)
* BLACKMAX-N, BLACKMAX-O, BLACKMAX-N-LP, BLACKMAX-NS,

BLACKMAX-NS-LP, XMAX, MICROMAX,MICROMAX-LP, ICROMAX-PLIS,MICROMAX-PLUS-LP, iMRI Instrument System (*see fsn 13237*)

* Star Excimer Laser System
* CODMAN Medstream Infusion Pump
* Transpedicular Schanz Screw (*see fsn 13436*)
* Carescape B650 Patient Monitor, Carescape B850 Patient Monitor (*see fsn 13450*)
* NordiPen 5 mg, 10 mg and 15 mg (*see fsn 13477*)
* Sinus-XL Stent (*see fsn 13493*)
* Suction Wand
* Carestream DRX-Evolution (*see fsn 13578*)
* Infusion-Perfusion-Transfusion sets (*see fsn 13592*)
* iViewC (*see fsn 13593*)
* FUJIFILM Digital Mammography System AMULET
* Edwards EndoReturn Arterial Cannula
* Sarns Centrifugal Pumping System - Battery, 220V
* Califomia Medical Laboratories Low Aortic Root Cannulae and Retrograde Cardioplegia Cannulae (*see fsn 13691*)
* H749RB4400150 - Flextome Cutting Balloon Monorail Microsurgical Dilatation Device M001BPM4015140F0 - Small Peripheral Cutting Balloon Monorail Microsurgical Dilatation Device
* ANASTAFLO INTRAVASCULAR SHUNT
* ADROIT 6F Guiding Catheter (*see fsn 13757*)
* CHEX Single Use Circular Stapler for Rectal Prolapse or Haemorrhoids (High Volume) (*see fsn 13775*)
* Terumo tubing sets

1. **Etudes cliniques / *Klinische studies:***

16 études ont été présentées / *16 studies werden gepresenteerd*

1. **Varia :**

2 dossiers d’incident ont été présentés / *2 incidenten dossiers werden gepresenteerd*

* 14021 : Terumo - COBE® Spectra Bone Marrow Processing Set
* 12723 : Terumo - TerumoR Advanced Perfusion System 1

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La réunion s’est clôturée à 14h35  
De vergadering wordt voor gesloten verklaard om 14u35.

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| La prochaine réunion de la Commission d’évaluation des dispositifs médicaux aura lieu le:  *De volgende vergadering van de Evaluatiecommissie voor medische hulpmiddelen gaat door op :*  **07/11/2013 : Salle/Zaal 06D285**  à 13h  *om 13u* |