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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 13 Mars 2014  Verslag van de vergadering van 13 Maart 2014 |

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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 |  | Emmanuelle Gay | |  | | | Maries Merken |  | Rita Cornélis | |  | | | Guibert Crèvecoeur |  | Jean-Claude Mignolet | |  | | | Isabelle De Pau ad it. Tom Clarijs | E / V | Annie Vanderlinck | |  | | | Guido Van Nooten | P/A Président | Yves Taeymans | |  | | | Hein Heidbüchel |  | Rik Willems | |  | | | Kristel De Vogelare |  | Daniel Mojet | | P / A | | | 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 E / V | |  | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps E / V |  | Fien Aerts | |  | | |  |  | Carole Absil | |  | | | Bart Mersseman |  | Marine Debaut E / V | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Vanackere Sébastien | Cédric Vandenbroucke | | Eglem Steve | |  | | Julie Roothooft | Lambot Damien | | Dejehansart Aline | |  | | Badisco Liesbeth |  | |  | |  | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

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Le président ouvre la réunion à 13h00. Le quorum n’est pas atteint.

*De voorzitter opent de vergadering om 13u00. Het quorum werd niet bereikt.*

1. **Ordre du jour  / *Dagorde***

Approuvé / goedgekeurd

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**

2 dossiers ont été présentés oralement durant cette séance de la Commission d’Evaluation :

2 dossiers werden mondeling voorgesteld tijdens deze vergadering van de Evalutatiecommissie.

**Dossier 14526: HeartWare Ventricular Assist System (heartWare)**

**Dossier 14749: LAP-BAND Adjustable Gastric Banding System (Allergan)**

69 FSCA soumis à la Commission d’Evaluation / 69 FSCAs warden voorgelegd aan de EvaluatieCommissie:

* AvantGuard 1200 (see fsn 9475)
* DDU-100 Series AED sold under the brand name Lifeline AED and Lifeforce AED (see fsn 9542)
* PE Alpha Hooded Insert HH/28; Model 01.00010.308; Lot 2463499 PE Alpha Hooded Insert LL/28; Model 01.00010.312; Lot 2462484

Durasul alpha Insert Neutral KK/36; Model 01.00013.711; Lot 2541553 Durasul Alpha Insert With Rim II/28; Model 01.00013.309; Lot 2541785

Durasul Alpha Insert Neutral GG/28; Model 01.00013.207; Lot 2541769 Durasul Alpha Insert With Rim MM/28; Model 01.00013.313; Lot 2541789 (see fsn 9909)

* Eclipse Treatment Planning System (see fsn 10034)
* EUROVIT COMPRESSE ABSORBANTE 10X20 CM STERILE PAR PIECE
* AQUARIUS with RCA (see fsn 10535)
* Olympus ETD/ Olympus miniETD (see fsn 11253)
* Single Use Laryngoscope / RUSCH Macintosh Laryngoscope Disp.Metallic Kit All Sizes (see fsn 11316)
* GemStar Optional Bolus Cord (see fsn 11361)
* Coccoon C2A (see fsn 11435)
* AMS 800 Urinary Control System (see fsn 12851)
* Latex-Free Extension Set with Locking Luer (see fsn 13078)
* STERRAD CYCLESURE 24 Biological Indicator (see fsn 13153)
* Epix Laparoscopic Graspers (see fsn 13270)
* BD Plastipak 50ML Luer Lok – Sterile (see fsn 13499)
* Easy Life Balloon
* Fluoroscan Mini C-arm (see fsn 13551)
* IMPAX DB Server 5.2 (see fsn 13793)
* Cognis CRT-D, Teligen VR ICD and Teligen DR ICD (see fsn 13845)
* multiFiltrate (see fsn 13875)
* Discovery MR750 3.0T, Discovery MR450 1.5T, Optima MR450w 1.5T (see fsn 13899)
* 2M81537K - COLLEAGUE TRIPLE CHANNEL MONOCHROME PUMP ENGLISH V1.7, 2M91617 - COLLEAGUE SINGLE CHANNEL CXEPUMP V1.7, 2M91637 - COLLEAGUE TRIPLE CHANNEL CXEPUMP V1.7, 2M81517K - COLLEAGUE SINGLE CHANNEL MONOCHROME PUMP ENGLISH V1.7, CNM81517 - COLLEAGUE SINGLE CHANNEL MONOCHROME PUMP, SWEDISH V1.7, CNM81537 - COLLEAGUE TRIPLE CHANNEL MONOCHROME PUMP, SWEDISH V1.7, DNM81517 - COLLEAGUE SINGLE CHANNEL MONOCHROME PUMP FRENCH V1.7, DNM81537 - COLLEAGUE TRIPLE CHANNEL MONOCHROME PUMP FRENCH V1.7, GNM81517 - COLLEAGUE SINGLE CHANNEL MONOCHROME PUMP, DAN/NOR V1.7, GNM81537 - COLLEAGUE TRIPLE CHANNEL MONOCHROME PUMP, DAN/NOR V1.7, HNM81517 - COLLEAGUE SINGLE CHANNEL MONOCHROME PUMP, GERMAN V1.7, HNM81537 - COLLEAGUE TRIPLE CHANNEL MONOCHROME PUMP, GERMAN V1.7, WNM81517 - COLLEAGUE SINGLE CHANNEL MONOCHROME PUMP, DUTCH V1.7, WNM81537 - COLLEAGUE TRIPLE CHANNEL MONOCHROME PUMP, DUTCH V1.7 (see fsn 13929)
* ENDOBON XENOGRAFT GRANULES 0,5ML (see fsn 13933)
* Obalon Inflation System Accessories (see fsn 13945)
* ClinActiv and Clinactiv + (see fsn 13963)
* Versys Hip System Cemented Revision/Calcar Femoral Stem, Versys Heritage Hip Prosthesis Femoral Revision Stem (see fsn 14019)
* A-dec 311 Chair, A-dec 361 Support Centre, A-dec light post & A-dec 7285 Radius Cuspidor (see fsn 14025)
* Contoura 1 000/1 080 (see fsn 14042)
* ADM MDM Ball Impactor Tip and ADM Rim Impactor Tip (see fsn 14046)
* da Vinci Si Surgical System Surgeon Console / Intuitive Surgical (see fsn 14058)
* TransRadial Artery Access Kit (see fsn 14062)
* MobileDiagnost wDR (see fsn 14119)
* Ratchet Handles used with the Trinica ALP System (see fsn 14127)
* Surgical procedure kit, dental, implant/prosthesis (see fsn 14178)
* CARINAsim control system +CARINAiso control system (see fsn 14198)
* NU-CIDEX (see fsn 14210)
* Rickham Style Reservoir (see fsn 14281)
* 3D Optical Coherence Tomography (see fsn 14284)
* NOVATECH GSS (see fsn 14287)
* REPLY, ESPRIT, FACIL (see fsn 14300)
* Spine & Trauma 3D (see fsn 14305)
* GemStar Docking Station (see fsn 14309)
* HT Connect Peripheral Guidewire (see fsn 14317)
* AMPLATZER Septal Occluder (see fsn 14322)
* SunTech Orbit ABP Cuffs (see fsn 14327)
* Toshiba (see fsn 14337)
* STERRAD Booster, STERRAD Adaptor (see fsn 14349)
* CARESTREAM and KODAK (see fsn 14356)
* Eclipse, ARIA Radiation Oncology, Acuity (see fsn 14388)
* Hemolung Cartridge Kit (see fsn 14390)
* Compressor mini (see fsn 14397)
* HP M.B.T. Keel Punch Knee Instrument (see fsn 14405)
* RM Pressfit cup TiCP vitamys 52/36 and 48/28 (see fsn 14428)
* Axxess (see fsn 14430)
* ARTIS Q (see fsn 14488)
* GEMINI TF PET/CT 16 and GEMINI TF PET/CT 64 Software Version 3.5.1, GEMINI TF PET/CT 16 and GEMINI TF PET/CT 64 Software Version 3.5.1.1, GEMINI TF PET/CT 16, GEMINI TF PET/CT 64, GEMINI TF Ready and GEMINI LXL Software Version 3.5.2, GEMINI TF PET/CT 16 and GEMINI TF PET/CT 64 Software Version 3.5.2.1, GEMINI TF Big Bore Software Version 3.6; GEMINI TF Big Bore Software Versions 3.6.1 and 3.6.2, TruFlight Select systems Software Version V3.5.3 (see fsn 14511)
* GEMINI TF Big Bore PET/CT (see fsn 14513)
* STERRAD 50, 100S, NX Sterilisation Systems (see fsn 14515)
* Freka Intestinal Tube for PEG (see fsn 14548)
* Procare B20 Patient Monitor, B30 Patient Monitor, Procare B40 Patient Monitor, B40 Patient Monitor (see fsn 14557)
* Midface Distractor, compl., distr. L 40mm, TAN (see fsn 14635)
* Aisys and Avance, Avance CS2, Amingo (Germany only) anaesthesia machines, Aespire, Aestiva (see fsn 14649)
* Anspach Short Carbide Cutting Burrs (see fsn 14677)
* TECNIS iTec Preloaded Delivery System (see fsn 14670)
* 840 Ventilator, 740 & 760 Ventilator systems (see fsn 14681)
* Paul Hartmann Heidenheim (see fsn 14752)
* MINISEND - LUER LOCK CAP (see fsn 14762)
* Cortex Screw 4.5 mm, self-tapp., L 44+46 mm, SSt (see fsn 14764)
* DePuy CMW 2 Gentamicin Bone Cement (see fsn 14778)
* LUTDNIX' .014" and .035' DCB PTA Catheter (see fsn 14818)
* CARTOUNIVU MODULE (see fsn 14826)

1. **Etudes cliniques / *Klinische studie***

18 études ont été présentées / 18 studies werden gepresenteerd

1. **Varia**

Le Président ne pourra être présent lors de la séance de la commission du 3 Avril 2014. Il prendra contact avec le prof. Taeymans afin de se faire remplacer. / De Voorzitter kan niet aanwezig zijn tijdens de vergadering van de Commissie van 3 april 2014. Hij zal contact opnemen met prof. Taeymans om hem te vervangen.

La réunion s’est clôturée à 14h00  
De vergadering wordt voor gesloten verklaard om 14u00.

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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 :*  **03/04/2014 : Salle/Zaal 06D288**  à 13h00  *om 13u00* |