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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 5 Décembre 2013  Verslag van de vergadering van 5 December 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 | P/A | 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 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 | |  | | | 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 | Cédric Vandenbroucke | | Eglem Steve | |  | | Julie Roothooft | Sibylle Watteeuw | |  | |  | | Schuyvinck Anne | Jauniaux Alexandre | |  | |  | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

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Le président ouvre la réunion à 13h10. Le quorum n’est pas atteint.

*De voorzitter opent de vergadering om 13u10. 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:*

* Approbation des dates des Commissions de 2014 / Goedkeuring van data voor de commissies van 2014
* Signature de la DoI 2014 / Ondertekening van de DOI 2014

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

Approuvé / *Goedgekeurd*

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

Euromy – Medde (2 dossiers tangents pour Mr Bart Mersserman)

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

Nihil

1. **Incidents**
2. dossiers ont été présenté oralement durant cette Commission d’Evaluation. / 5 *dossiers werden mondeling voorgesteld.*

53 FSCA soumis à la commission / 53 FSCAs werden voorgelegd aan de commissie:

* Axiom Iconos R200 VD00D SW
* Equalizer TM Occlusion Balloon Catheter
* Advance Canal Filling Extension 11mmx140mmm, 11mmx140mm, 13mmx140mmm
* GYNECARE MORCELLEX Tissue Morcellator
* Reflex Hybrid Screw Extractor
* ISKD Intramedullary Skeletal Kinetic Distractor (limb lengthener)
* VA20A Service Pack 3
* BD Plastipak Syringe
* BD Plastipak Syringe
* Responder 2000 defibrillator/monitor
* Bard Magnum Disposable Biopsy Core Needles 16 Gauge
* Hintegra R Talar cutting guide
* GE Voluson E6, GE voluson E8, and GE voluson E8 Expert Diagnostic Ultrasound Systems
* syngo Imaging XS
* HEARTSTART MRX , monotor/defibrillator
* Advantage R 2-Button Turbo Handpiece
* CAS Power Cord Sesamoid Plasty
* Tecnis One-Piece
* Latitude patient management server software (see fsn 9179)
* AMS 800 Control Pump (see fsn 9714)
* Smith & Nephew, 560P High Definition Camera Control
* BIRMINGHAM HIP Modular Head (see fsn 12095)
* OMRIX PRESSURE REGULATOR / Applicator and Pressure Regulator for:EVICEL, Solutions for Sealant, QUIXIL Fibrin Sealant (Human) (see fsn 12154)
* REA Azalea Base (see fsn 12376)
* Invacare FDX (see fsn 12378)
* Patient Data Module (see fsn 12619)
* CEM Nosecone (see fsn 12628)
* Carestream DRX-Evolution system (see fsn 12764)
* Restylane SubQ Lido (see fsn 12788)
* LIFEPAK CR Plus and LIFEPAK EXPRESS (see fsn 12836)
* HBS 2 Mini Schraube, kurz 22mm (see fsn 12947)
* Mevatron/Primus/Oncor/Artiste (see fsn 12997)
* Segmented Cylinder Applicator Set (see fsn 13089)
* ProcedurePak (see fsn 13141)
* DuraGen Dural Graft Matrix, DuraGen Plus Adhesion Barrier Matrix

Suturable DuraGen Dural Regeneration Matrix + Layershield Adhesion Barrier Matrix + Neurawrap Nerve Protector, NeuraGen Nerve Guide (see fsn 13182)

* Codman & Shurtleff, Inc. 50-8081 Collins Radioparent Sternal Blades Nylon (see fsn 13183)
* da Vinci Surgical System (see fsn 13223)
* Segmented Cervix Applicator Set GM1104540 (see fsn 13241)
* Trima Accel System (see fsn 13280)
* Medullary Reamers 6.0 mm to 10.5 mm (see fsn 13316)
* RadialSource Transradial Access Kit (see fsn 13335)
* BioMend Absorbable Collagen Membrane, BioMend Extend Absorbable Collagen Membrane, CollaCote Absorbable Collagen Wound Dressing for Dental Surgery, CollaPlug Absorbable Collagen Wound Dressing for Dental Surgery, CollaTape Absorbable Collagen Wound Dressing for Dental Surgery (see fsn 13368)
* LeMaitre Stent Guide; Glow'N Tell Tape (see fsn 13388)
* Titanium cancellous screw 5 lg 30 (see fsn 13397)
* A-dec 200 Dental Chair System\_200 (see fsn 13623)
* STERRAD 100NX Cassette (see fsn 13674)
* Genius Eco with analysis system and Factum (see fsn 13716)
* MAQUET Oxygenators (see fsn 13726)
* GENESIS II PS and MB Insert (see fsn 13835)
* Angiography Contrast Delivery System (see fsn 13851)
* FMS tubing codes 284649 and 281142 (see fsn 13853)
* PORT-A-CATH? and PORT-A-CATH II implantable venous and arterial access systems and introducer sets. (see fsn 13907)
* STERRAD 200 (see fsn 13949)
* EMBOL-X Glide Protection System (see fsn 13964)
* optimys Opening Broach bent (see fsn 13987)
* Cobe Spectra BMP / COBE Spectra Bone Marrow Processing Set (see fsn 14021)
* STERRAD Booster and Adaptor (see fsn 14024)
* Carescape Monitor B450 (see fsn 14026)
* Trima Accel System (see fsn 14128)
* Anaconda ONE-LOK Bifurcate Body; Anaconda Bifurcate Body (see fsn 14137)

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

20 études ont été présentées / 20 studies werden grepresenteerd

1. **Varia**

Approbation des dates des prochaines Commission d’Evaluation (2014) / Goedkeuring van de data voor de volgende Evaluatiecommissies (2014) :

1. 6 février / *februari*
2. ~~6 mars~~ 13 mars / *maart*
3. 3 avril / *april*
4. 8 mai / *mei*
5. 5 juin / *juni*
6. 3 juillet / *juli*
7. ~~7 août /~~ *~~augustus~~*
8. 4 septembre / *september*
9. 2 octobre / *oktober*
10. 6 novembre / *november*
11. 4 décembre / *december*

Renouvellement des DoI pour 2014/ Hernieuwing van de DOI voor 2014 :

Les Déclarations d’Intérêts vont être envoyées en janvier 2014 pour l’année 2014 / Belangenverklaringen voor het jaar 2014 zullen worden verstuurd in januari 2014.

La réunion s’est clôturée à 15h00  
De vergadering wordt voor gesloten verklaard om 15u00.

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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 :*  **06/02/2014 : Salle/Zaal 06D288**  à 13h00  *om 13u00* |