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| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 04 décembre 2014  Verslag van de vergadering van 04 december 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 | | P / A | | | Awatif Jebari | E / V | Emmanuelle Gay | | E / V | | | 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 | |  | | | 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 | E / V | Tinne Leysen | |  | | | Christine Barzin |  | Jan Saevels | | E / V | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps | E / V | Fien Aerts | |  | | |  |  | Carole Absil | |  | | | Bart Mersseman | P / A | Marine Debaut | | P / A | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Lambot Damien | Vandenbroucke Cédric | | Van de Vijver Pieter | |  | | Roothooft Julie | Decaluwé Kelly | |  | |  | | Badisco Liesbeth  Watteeuw Sibylle | Eglem Steve  Driesmans Christof | |  | |  | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

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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***

Toevoeging van 3 variapunten:

* Aanwezigheid van mycobacteriën in een Heater cooler unit van de firma Sorin Group Deutschland
* Nanostim Leadless Pacemaker van St. Jude
* Thermocool SmartTouch Uni-Directional Navigation Catheter (Biosense Webster)

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

Approuvé / goedgekeurd

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

nihil

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

Zie punt 7 varia

1. **Incidents**

1 dossier werd mondeling gepresenteerd tijdens deze Evaluatiecommissie

**Dossier 16583:** GS DF60-Schale GS Corpatch easy neonate (Leonhard Lang Medizintechniek GmbH)

24 FSCA ont été soumis à la Commission d’Evaluation / 24 FSCAs werden voorgelegd aan de Commissie.

* Terumo Advanced Perfusion System 1
* 1 Litre Receptal System (Lid and Liner) (see fsn 13008)
* Modal 8870 Solfware Application Card (see fsn 14011)
* Mosaic Aortic Bioprosthesis (see fsn 14603)
* Powerheart G5 AED (see fsn 14698)
* ReTurn7500, ReTurn7400 (see fsn 15109)
* Discovery MR450, Discovery MR750 Optima MR450w, Optima MR 450w equipped with GEM option, Discovery MR750w, Discovery MR750w equipped with GEM option PROGRESSA MATTRESS (see fsn 15360)
* Discovery MR450, Discovery MR750, Optima MR450w, Optima MR 450w equipped with GEM option, Discovery MR750w, Discovery MR750w equipped with GEM option (see fsn 15443)
* Orbital Rim Plate, 1.3 curved, 9 holes, Pure Titan (see fsn 15593)
* AGFA Digital Radiography X-Ray system DX-D 100 (see fsn 15710)
* Ingenia, Intera and Achieva MR Systems on R5.1.1 and R5.1.2 (see fsn 15723)
* IntelliSave AX700 (see fsn 15849)
* Coseal Surgical Sealant (see fsn 15892)
* T-PAL, Technique Guide (see fsn 15935)
* da Vinci S Surgical System, da Vinci Si Surgical System, da Vinci Sie Surgical System (see fsn 15974)
* Discovery XR656 (see fsn 16052)
* Nelaton and Nelaton Robinson Catheters (see fsn 16109)
* Symbia S and T Series camera systems (see fsn 16131)
* Artis zeego (see fsn 16253)
* VA-LCP Dorsal Distal Radius-T-Plate (see fsn 16306)
* MultiDiagnost Eleva with Flat Detector (see fsn 16376)
* GENESIS II Sawblades (see fsn 16377)
* VA-LCP Volar Distal Radius Plate 2.4, extraarticular, left, 3+4 holes, length 45 mm, Pure Titanium, sterile (see fsn 16385)

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

10 études ont été présentées / 10 studies werden gepresenteerd

1. **Varia**
2. Aanwezigheid van Mycobacteriën in een Heater cooler van de firma Sorin Group Deutschland
3. Heartstart XL + Defibrillator/Monitor van de firma Philips Medical system (ventrikel stimulatie)
4. Nanostim Leadless Pacemaker St. Jude
5. Thermocool SmartTouch Uni-Directional Navigation Catheter (Biosense Webster)
6. Herbenoeming van de Leden van de Evaluatiecommissie

Un courrier sera envoyé d’ici peu aux universités et autres partenaires de la Commission d’Evaluation. Ce courrier est une demande de renouvellement ou de remplacement de mandat des membres de la Commission pour les 5 prochaines années. En parallèle, un email sera envoyé aux membres régulièrement présents pour qu’ils puissent se signaler auprès de leur Direction et faire part de leur motivation.

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 :*  **08/01/2015 : Salle/Zaal Floralia**  à 13h00  *om 13u00* |