|  |
| --- |
|  |
| **Commission d’évaluation des dispositifs médicaux**  **Evaluatiecommissie voor medische hulpmiddelen**  Compte-rendu de la réunion du 05 Juin 2014  Verslag van de vergadering van 05 juni 2014 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **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 | P / A | 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 | 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 | | E / V | | | Ludo Willems |  | Dominique Toye | |  | | | Annick Verbiest |  | Philippe Noirhomme | |  | | | Jacques Destiné |  | J-L Vanoverschelde | |  | | | Olivier Debeir |  | Marie-José Tassignon | |  | | | Wim Verlinden |  | Thierry Descamps | |  | | | Dominique Wouter |  | Tinne Leysen | |  | | | Christine Barzin |  | Jan Saevels | | E / V | | | Anne-Sophie Grell |  | Alex Rijnders | |  | | | Marc Cumps | E / V | Fien Aerts | |  | | |  |  | Carole Absil | | E / V | | | Bart Mersseman |  | Marine Debaut | |  | | | **Représentants de l’AFMPS - Vertegenwoordigers van het FAGG** | | | | | | | Roisin Thierry | Cédric Vandenbroucke | | Eglem Steve | |  | | Julie Roothooft | Badisco Liesbeth | | Dejehansart Aline | |  | | Vidick Déborah | Decaluwe Kelly | |  | |  | |  | | | | | | |  | | | | | | |  | | | | | | |  | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

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 moyennant l’ajout d’un point varia concernant l’acide hyaluronique / goedgekeurd rekening houden met een extravaria punt betreffende de Hyaluronzuur

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 cette Commission d’Evaluation :

2 dossiers werden mondeling gepresenteerd tijdens de zitting van de Evaluatiecommissie:

* Dossier 15178: Physiomesh (Johnson and Johnson)
* Dossier 14993: Freka Intestinal Tube Fr9 for 15 FR (Fresenius Kabi)

36 FSCA soumis à la Commission / 36 FSCAs werden voorgelegd aan de Commissie

* XVI Digital imager, radiation therapy (see fsn 10471)
* Magnus Carbon-Fibre Table Top (see fsn 11241)
* Maxcem Elite
* GemStar infusion system
* Aisys, Amingo (Germany only), Avance, and Avance CS2 (see fsn 14193)
* Dialox (see fsn 14204)
* HomeChoice / HomeChoice Pro (see fsn 14236)
* Large and Mega Needle Drivers / Endowrist Instruments (see fsn 14346)
* Corevalve Delivery System, Delivery Catheter System(DCS), Accutrak (see fsn 14360)
* Precision 500D, Legacy, Prestilix, Monitrol, RFX, SFX, Tilt-C, Prestige VH, Prestige SI, Prestige SII (see fsn 14376)
* STERRAD CYCLESURE 24 Biological Indicator
* POWERFLEX? PRO PTA Dilatation Catheter (see fsn 14497)
* Ventilogic LS (see fsn 14498)
* CUSA Excel CEM Nosecone (see fsn 14530)
* PROPHYflex 3 (see fsn 14612)
* CyberKnife Robotic Radiosurgery System (see fsn 14714)
* KAMRA Corneal Inlay (see fsn 14770)
* RHK Knee Resurfacing Femur (see fsn 14816)
* Treatment-Pack (see fsn 14833)
* PENTARAY NAV CATHETER / Pentaray NAv Eco Catheter (see fsn 14862)
* Infinia and Infinia Hawkeye Nuclear Medicine systems, Millennium VG, VG Hawkeye and VariCam Nuclear Medicine systems, Helix Nuclear Medicine systems (see fsn 14869)
* CERAMENT SPINE SUPPORT (see fsn 14957)
* Equipment Carts (see fsn 15067)
* Renma PTA Dilatation Catheter (see fsn 15100)
* Threaded Red. Tool (see fsn 15153)
* Radiation Treatment Planning System (see fsn 15168)
* Astron Pulsar (see fsn 15200)
* NovaGold High Performance Guidewire (see fsn 15237)
* CVC/PSI KIT, MULTI-LUMEN/PSI KIT, PSI KIT, PSI SET (see fsn 15280)
* DigitalDiagnost (see fsn 15282)
* Craniomaxillofacial (CMF) Distraction System (see fsn 15339)
* proGav en GAV shunt systeem (see fsn 15398)
* IntelliVue Patient Monitor MP2, X, MP5, MP5T, MP20, MP30, MP40 and MP50 (see fsn 15404)
* MGuard Prime Coronary Stent System Embolic protective stent (see fsn 15419)
* Filet Ventralight ST Bard avec système de positionnement Echo PS et filet Composix L/P Bard avec système de positionnement Echo PS (see fsn 15437)

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

15 études ont été présentées / 15 studies werden gepresenteerd.

1. **Varia**

Acide Hyaluronique : Préparer une communication à publier sur le site de l’AFMPS / Een communicatie voorbereiden om te publiceren op de website van het FAGG.

La réunion s’est clôturée à 14h30  
De vergadering wordt voor gesloten verklaard om 14u30.

|  |
| --- |
| 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 :*  **03/07/2014 : Salle/Zaal Vivaldi**  à 13h00 / *om 13u00* |